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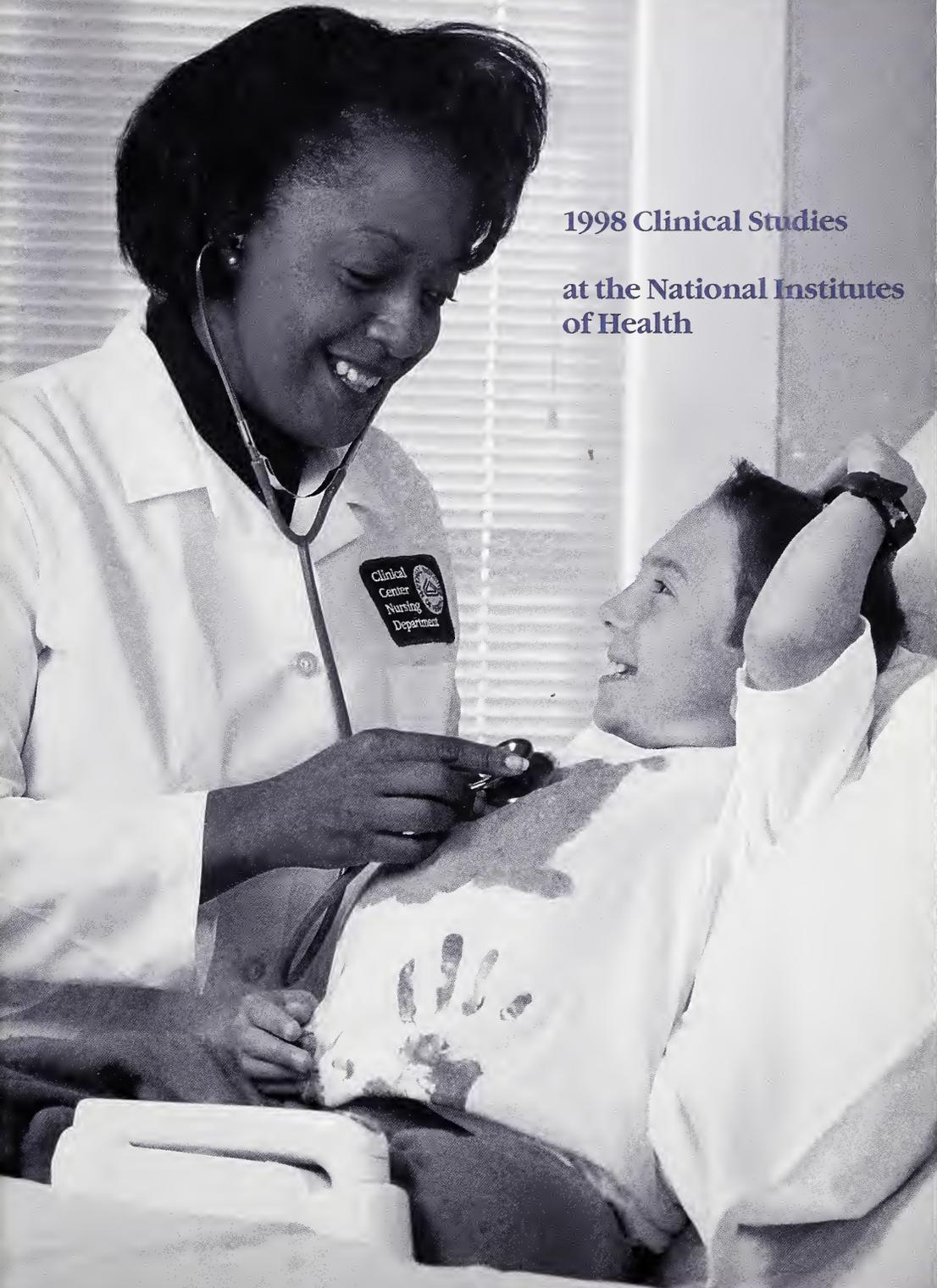
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**1998 Clinical Studies
at the National Institutes
of Health**



Institutes

NCI	National Cancer Institute
NHGRI	National Human Genome Research Institute
NEI	National Eye Institute
NHLBI	National Heart, Lung, and Blood Institute
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAD	National Institute of Allergy and Infectious Diseases
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NICHD	National Institute of Child Health and Human Development
NIDCD	National Institute on Deafness and Other Communication Disorders
NIDR	National Institute of Dental Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIDA	National Institute on Drug Abuse
NIMH	National Institute of Mental Health
NINDS	National Institute of Neurological Disorders and Stroke

Institute Contacts

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Clinical Center Director

CC	John I. Gallin, M.D.	10/2C128	301-496-4114
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*NIH's mailing address is National Institutes of Health, Bethesda, MD 20892-1170.

**NIDA's Addiction Research Center mailing address is ADC, Building C, 4940 Eastern Avenue, Baltimore, MD 21224.

1998 Clinical Studies

The Warren Grant Magnuson Clinical Center

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Public Health Service
National Institutes of Health

Clinical Center
Bethesda, Maryland 20892-1170

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From the Director

Through clinical research, medical investigators develop and refine treatments that cure and prevent disease. At the Warren Grant Magnuson Clinical Center at the National Institutes of Health, our work is devoted entirely to the conduct of that research.

In 1997, groundbreaking ceremonies for our new building, the Mark O. Hatfield Clinical Research Center, signaled an era of significant growth and expansion for clinical research at NIH. I invite you to look over this collection of current studies and consider collaborations with us during this exciting time.

Patients referred by their physicians may participate in studies that examine such diseases as cancer, arthritis, heart disease, and Alzheimer's. NIH investigators and our highly specialized health care professionals form a unique team offering care and support for patients who take part in the nearly 1,000 studies carried out here each year.

We update this overview annually to help you learn more about opportunities to take part in clinical research at the nation's foremost medical research complex. More detailed information on our work is available on the NIH Clinical Center's web site ("Current Clinical Research Studies" at www.cc.nih.gov).

Our Patient Recruitment and Referral Center staff are ready to answer your questions. Call them at 1-800-411-1222 (301-496-4891 in the Washington, DC, metro area). Their e-mail address is prrc@cc.nih.gov.

I hope you find this booklet useful. Your participation in clinical research at NIH is welcome and critical to the advancement of medical knowledge.

John I. Gallin, M.D.

Director, Warren Grant Magnuson Clinical Center

Referring a Patient

Patients are admitted to the Clinical Center at the National Institutes of Health only on referral by a physician or dentist and only for research purposes. A complete diagnosis and medical history is necessary for admission.

Please contact the Patient Referral and Recruitment Center at 1-800-411-1222 to find out if your patient's diagnoses may be of interest to investigators. If the patient's disease is under active investigation, physicians may be asked to submit the diagnosis and medical history in writing to the principal investigator. Direct contacts are listed for most studies in this booklet.

Patients accepted to participate in a clinical research protocol are not asked to pay for their medical, surgical, and other hospital care. First-time patients must usually pay for their own transportation to the hospital in Bethesda, Maryland. Financial assistance for subsequent visits may be subsidized by the institute based on need. The Clinical Center Social Work Department is available to help prospective patients with personal problems concerning admission. For more information, contact the Social Work Department at 301-496-2381.

Eligibility Requirements

1. The patients must be referred by a physician or dentist in private practice, hospital, clinic or other medical organization.
2. The patient's specific disease or condition must be under active investigation by NIH physicians at the time of admission.
3. Each institute considers age, weight, sex, general health and length of waiting list of qualified patients as criteria for admission. The possibility of long-term inpatient stays and extended follow-up is also considered. Apart from these medical considerations, there are no other restrictions based on race, creed, age, sex, or color.
4. Patients must have a responsible understanding of their role in a research protocol.

Length of Stay

Admission to the Clinical Center is for research purposes only. Patients will return to the care of their referring physicians or institution, or to their families, when their participation in a protocol ends and their medical condition permits. Each institute's clinical director makes this determination.

1998 Clinical Studies at the National Institutes of Health

Aging

Aging, Growth Hormone/Sex Steroid Intervention in Aging

Eligibility Requirements

Healthy women and men age 65 or older, non-smokers.

Treatment/Procedures

Supplementation of growth hormone and/or sex steroid (estrogen or testosterone). Standard laboratory tests, body composition studies, DEXA scan, VO₂ Max, KIN-COM, cardiac MRI and echocardiogram, anthropomorphic measurements.

Contact

Katharine Pabst, C.R.N.P. 410-550-1057
National Institute on Aging

Alzheimer's Disease

Eligibility Requirements

Patients with a diagnosis of possible or probable Alzheimer's disease including preclinical, mild, or moderately advanced stages.

Treatment/Procedures

Drug therapy aimed at treating symptoms and slowing disease progression; biochemical studies aimed at eliciting pathogenesis as well as preventive and treatment modalities.

Contact

Marjorie Gillespie, R.N. 301-496-4604
National Institute of Neurological Disorders and Stroke

Alzheimer's Disease

Eligibility Requirements

Patients with Alzheimer's disease of mild to moderate impairment; no complicating cerebrovascular disease.

Treatment/Procedures

Neuropsychology; structural MRI; MR spectroscopy; PET scanning with drug modulation; cerebrospinal fluid examination.

Contact

Carol Kinslow 301-496-1272
National Institute on Aging

Alzheimer's Disease/Dementia of the Alzheimer's Type

Eligibility Requirements

Patients must show signs of dementia of the Alzheimer's type.

Treatment/Procedures

Drug study: patients receive one year of tetrahydrobiopterin and one year of placebo treatment; procedures: laboratory test, cognitive tests, and motor tests.

Contact

Carol Kinslow 301-496-1272
National Institute on Aging

Alzheimer's Disease/Dementia of the Alzheimer's Type

Eligibility Requirements

Patients should have a diagnosis of mild to moderate dementia and be in good general health.

Treatment/Procedures

After a thorough diagnostic evaluation with cognitive, physiologic and brain imaging studies, patients may be offered further research diagnostic tests and short and long-term treatment studies with investigational agents. Long-term follow-up is available in collaboration with local primary physicians.

Contact

K. Sue Bell, M.S.W. 301-496-5111 or 496-3421
National Institute of Mental Health

Alzheimer's Disease/Family Member Study

Eligibility Requirements

Patients must be over the age of 50 years and normal cognitively but have at least one first degree relative (sister, brother, or parent) with dementia of the Alzheimer's type.

Treatment/Procedures

After a careful baseline evaluation, subjects will be tested with a series of genetic markers, brain imaging tests, possible medication tests, and a cognitive battery. Follow-up studies will be offered on a yearly basis.

Contact

Judy Friz, M.A. 301-496-0948 or 496-3421
National Institute of Mental Health

Bereavement/Grief**Eligibility Requirements**

Adults over the age of 50 years in good general health who have suffered the death of spouse *within the past one to three months*.

Treatment/Procedures

After a screening evaluation, subjects will be tested with a series of biochemical, cognitive, imaging and immunologic studies initially, and then followed monthly for 13 months after spousal death. Subjects will be offered treatment if depression occurs.

Contact

Larry Bauer, R.N. 301-496-6565 or 301-496-3421
National Institute of Mental Health

Dementia

See *Neurological Disorders and Stroke*.

Down Syndrome

See *Genetic and Inherited Diseases*.

Fragile X Syndrome

See *Genetic and Inherited Diseases*.

Alcohol Abuse

Alcoholism, Smokers, and Non-smokers

Eligibility Requirements

Alcoholics with no illicit or prescription drug use; no other medical problems; not pregnant; non-alcoholic controls.

Treatment/Procedures

Inpatient detoxification from alcohol; behavioral and biochemical effects of withdrawal from alcohol and/or smoking.

Contact

David T. George, M.D. 301-496-1860
National Institute on Alcohol Abuse and Alcoholism

Alcoholism and Domestic Violence

Eligibility Requirements

Repeated episodes of physical aggression toward significant others; no medical problems; not pregnant; non-alcoholic controls.

Treatment/Procedures

Behavioral and biochemical effects of Yohimbine administration.

Contact

David T. George, M.D. 301-496-1860
National Institute on Alcohol Abuse and Alcoholism

Alcoholism

Eligibility Requirements

Women alcoholics with no illicit or prescription drug use; no other medical problems; not pregnant; non-alcoholic controls.

Treatment/Procedures

Inpatient detoxification from alcohol; lumbar cerebrospinal fluid sample; MRI.

Contact

David T. George, M.D. 301-496-1860
National Institute on Alcohol Abuse and Alcoholism

Eriksonian Stages of Psychosocial Development

Eligibility Requirements

Individuals who are currently alcohol dependent, adult children of alcoholics with no current or past alcohol dependence and non-alcoholic controls, no major medical problems.

Treatment/Procedures

Physical exam/blood workup. Self-administered questionnaires for Eriksonian stages of psychosocial development.

Contact

Linda Doty, LCSW-C 301-496-1992

National Institute on Alcohol Abuse and Alcoholism

Allergies

Asthma

Eligibility Requirements

Mild to moderately severe asthma precipitated by allergies.

Treatment/Procedures

Outpatient studies to determine disease pathogenesis.

Contact

Dean Metcalfe, M.D.

Calman Prussin, 301-496-2165

National Institute of Allergy and Infectious Diseases

Arthritis (Musculoskeletal and Skin Diseases)

Arthritis, Early Inflammatory

Eligibility Requirements

Adults with swollen, painful joints of less than one-year duration; no evidence of gout, other crystal disease, or overt infection.

Treatment/Procedures

Randomized trial of antibiotic therapy; joint fluid aspiration; needle synovial biopsy; research bloods drawn and chlamydia cultures.

Contact

Cheryl Yarboro, R.N., B.S.P.A. 301-401-6409

Marianna L. Crane, R.N., N.P. 301-402-8679

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Arthritis, Psoriatic

Eligibility Requirements

Patients with psoriatic arthritis or normal individuals with a family history of psoriatic arthritis; patients refractory to standard therapies.

Treatment/Procedures

Subcutaneous interleukin 10; intravenous fludarabine; synovial and/or skin biopsy; research bloods drawn.

Contact

Dimitrios T. Boumpas, M.D. 301-496-4094

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Arthritis, Rheumatoid

Eligibility Requirements

Rheumatoid arthritis patients ages 18 years or older who are not allergic to tetracyclines.

Treatment/Procedures

Doxycycline 300mg or placebo intravenously for 14 consecutive days; blood tests; joint counts; questionnaires at baseline; 2-week, 6-week, and 12-week visits; study duration is 12 weeks.

Contact

Stanley R. Pillemer, M.D. 301-496-0434

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Arthritis, Rheumatoid (pregnant and recent postpartum females)

Eligibility Requirements

Pregnant and postpartum females with rheumatoid arthritis.

Treatment/Procedures

Research bloods drawn, urine collected.

Contact

Ronald L. Wilder, M.D., Ph.D. 301-496-3373
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Carney Complex/Primary Pigmented Adrenocortical Dysplasia (PPNAD)

See *Endocrine Disorders*.

Connective Tissue Disorders, Heritable

Eligibility

Individuals with known or suspected genetic disorders of the connective tissue and their family members of any age. Disorders studied include but are not limited to Marfan syndrome, Stickler syndrome, Ehlers-Danlos syndromes, contractural arachnodactyly, familial aortic ectasia syndrome, Shprintzen-Goldberg syndrome, MASS phenotype, Pseudoxanthoma elasticum, Nail-Patella syndrome, and cutis laxa.

Treatment/Procedures

Medical examination, imaging studies (including X-ray, MRI, CT, and echocardiography), ophthalmologic evaluation, orthopedic evaluation, blood drawn for genetic evaluation, and skin biopsy for genetic studies.

Contact

Clair A. Francomano, M.D. 301-402-8255
Kathy Peters, M.S. 301-402-9653
National Human Genome Research Institute

Familial Mediterranean Fever (FMF)

See *Genetic and Inherited Diseases*.

Genetic Metabolic Muscle Disease

Eligibility Requirements

Adult or juvenile patients with acid maltase deficiency or other genetic metabolic muscle disease.

Treatment/Procedures

Genetic counseling; magnetic resonance imaging; muscle biopsy; genetic analysis.

Contact

Paul H. Plotz, M.D. 301-496-1474

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Genodermatoses

Eligibility Requirements

Eligibility depends on specific skin condition (example: lamellar ichthyosis, epidermolytic hyperkeratosis—all affected individuals eligible; Darier's disease, Hailey-Hailey disease—may be eligible only to persons with positive family history, in which other family members are available for study).

Treatment/Procedures

Genetic counseling provided; procedures may include all or some of the following: history, physical, dysmorphology examination, blood or buccal swab, skin biopsy, clinical photographs, dental examination and panorex, bone x-rays, pelvic ultrasound, cytogenetics.

Contact

Sheri Bale, Ph.D. 301-402-2679

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Hermansky-Pudlak Syndrome

See *Endocrine Disorders*.

Lupus Erythematosus, Systemic

Eligibility Requirements

Adult patients with known or suspected systemic lupus, especially lupus nephritis.

Treatment/Procedures

Protocols for treatment with experimental approaches to immune modulation: genetic studies; skin, kidney, and/or bone marrow biopsies; research bloods drawn.

Contact

Dimitrios T. Boumpas, M.D. 301-496-4094

John H. Klippel, M.D. 301-496-3374

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Myositis, Juvenile-onset

Eligibility Requirements

Patients with juvenile dermatomyositis and other forms of myositis with onset during childhood (<18 years of age).

Treatment/Procedures

Magnetic resonance imaging; magnetic resonance spectroscopy; swallowing ultrasound; barium swallow; exercise testing; gait analysis; muscle strength and skin evaluation; research blood testing.

Contact

Lisa G. Rider, M.D. 301-827-0679

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Myositis (polymyositis, dermatomyositis, and related inflammatory myopathies)

Eligibility Requirements

Adults with active myositis.

Treatment/Procedures

Protocols for treatment with cytotoxic or other experimental anti-inflammatory medications; magnetic resonance imaging; muscle biopsy; research bloods drawn.

Contact

Paul H. Plotz, M.D. 301-496-1474

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Myositis or Scleroderma, Silicone-associated

Eligibility Requirements

Patients who developed myositis or scleroderma after silicone implants; normal volunteers with silicone implants.

Treatment/Procedures

Completion of questionnaire; blood drawing for research.

Contact

Frederick W. Miller, M.D., Ph.D. 301-827-0659

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Osteogenesis Imperfecta

Eligibility Requirements

Infants and toddlers with suspected type II, III or IV osteogenesis imperfecta; skin biopsy should **not** have been done.

Treatment/Procedures

Skin biopsy; genetic workup; examination of clinical characteristics over time; aggressive physical therapy; bracing; study of growth deficiency.

Contact

Elizabeth Hopkins, Research Nurse 301-496-0741
National Institute of Child Health and Human Development

Psoriasis

Eligibility Requirements

Selected patients 18 years or older with stable, plaque type psoriasis may be eligible for study.

Treatment/Procedures

Eight-week evaluation of topical antinflammin versus placebo cream.

Contact

John J. DiGiovanna, M.D. 301-402-1607
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Skin Cancer, Disorders of Cornification

See *Cancer*.

Sjögren's Syndrome

Eligibility Requirements

Patients with diagnosed or suspected primary Sjögren's syndrome.

Treatment/Procedures

Confirmation of diagnosis; studies of salivary gland function; treatments of the underlying exocrinopathy.

Contact

Philip C. Fox, D.D.S. 301-496-4278
National Institute of Dental Research

Cancer

AIDS-related Dermatoses

Eligibility Requirements

Patients with Kaposi's sarcoma, eosinophilic folliculitis, photosensitivity, psoriasis, and generalized pruritus associated with AIDS.

Treatment/Procedures

Procedures to determine etiology or confirm diagnosis; treatment as needed.

Contact

Andrew Blauvelt, M.D. 301-402-4167
National Cancer Institute

Angio Immunoproliferative Lesions

Eligibility Requirements

Patients 18 years old or older; grade I, II, and III angio immunoproliferative lesions; previously untreated.

Treatment/Procedures

Chemotherapy.

Contact

Barry L. Gause, M.D. 301-496-0901
National Cancer Institute/BRMP

Ataxia-Telangiectasia

Eligibility Requirements

Patients with ataxia-telangiectasia.

Treatment/Procedures

Thorough evaluation and intensive study of immunological function.

Contact

Thomas A. Waldmann, M.D. 301-496-6653
National Cancer Institute

Birth Defects

See *Cancer, Epidemiology*.

Bladder Cancer

Eligibility Requirements

Recurrent, superficial bladder cancer.

Treatment/Procedures

Endoscopic resection/intravesical therapy.

Contact

McClellan M. Walther, M.D. 301-402-2251
National Cancer Institute

Brain Tumor

Eligibility Requirements

Previously treated patients between 10-24 years of age with evidence of refractory disease.

Treatment/Procedures

Phase I/II therapy.

Contact

Attending Physician 301-402-0696
National Cancer Institute

Brain Tumor

Eligibility Requirements

High-grade glioma not previously treated with radiotherapy or chemotherapy.

Treatment/Procedures

Radiation response modifier 2-Chlorodeoxyadenosine administered via continuous IV infusion weekly with concurrent hyperfractionated radiation.

Contact

Brian Fuller, M.D. 301-496-5457
National Cancer Institute

Brain Tumor

Eligibility Requirements

Glioblastoma not previously treated with radiotherapy or chemotherapy.

Treatment/Procedures

Radiation response modifiers hydroxyurea and pentoxifylline administered via continuous infusion concurrently with hyperfractionated radiotherapy.

Contact

Brian Fuller, M.D. 301-496-5457
National Cancer Institute

Brain Tumor

Eligibility Requirements

Patients with primary brain tumors, including all grades of glioma and pituitary tumors.

Treatment/Procedures

Surgery and/or investigational therapy.

Contact

Edward H. Oldfield, M.D. 301-496-2921
National Institute of Neurological Disorders and Stroke

Brain Tumor

Eligibility Requirements

Patients with von Hippel-Lindau disease and an Endolymphatic Sac tumor.

Treatment/Procedures

Audiometry and therapy.

Contact

Edward H. Oldfield, M.D. 301-496-2921
National Institute of Neurological Disorders and Stroke

Brain Tumor

Eligibility Requirements

Patients with every type of intracranial tumor (emphasis on gliomas); both newly recognized and previously treated neoplasms are eligible; evaluation on an outpatient basis.

Treatment/Procedures

Assessment with PET (glucose metabolism) and magnetic resonance (MRI conventional imaging, spectroscopy, diffusion, perfusion) to determine grade of malignancy and to differentiate tumor-recurrence from treatment-related complications (e.g., radionecrosis).

Contact

Lucien Levy, M.D. 301-496-6801
National Institute of Neurological Disorders and Stroke

Breast Cancer**Eligibility Requirements**

Patients with stage IV breast cancer who have responded to chemotherapy.

Treatment/Procedures

High-dose chemotherapy with autologous marrow and peripheral blood stem cell transplant using blood stem cells genetically modified with the MDR (multidrug resistance) gene.

Contact

JoAnne Zujewski, M.D.
Kenneth H. Cowan, M.D., Ph.D. 301-496-4916
National Cancer Institute

Breast Cancer**Eligibility Requirements**

Stage II, III, IV breast cancer.

Treatment/Procedures

Patients with clinical stage II, III, or IV breast cancer will undergo a nuclear medicine PET scan before and after chemotherapy treatment to determine the role of PET scan as an imaging modality and measure the effect of chemotherapy.

Contact

David N. Danforth, Jr., M.D. 301-496-1533
National Cancer Institute

Breast Cancer**Eligibility Requirements**

Patients with stage III or stage IV breast cancer who are untreated, or after adjuvant therapy or induction therapy, demonstrate a partial response.

Treatment/Procedures

Dose-intensive chemotherapy (paclitaxel, cyclophosphamide) followed by high-dose chemotherapy (melphalan, etoposide) with autologous stem cell transplantation.

Contact

David Halverson, M.D. 301-402-3627
National Cancer Institute

Breast Cancer

Eligibility Requirements

Untreated patients with high risk stage II, stage III or metastatic breast cancer who will be receiving dose-intensive chemotherapy.

Treatment/Procedures

Prechemotherapy collection of T cells. Postchemotherapy modulation of T cell reconstitution by autologous T cell transplantation, patient specific p53 or ras anti-tumor vaccination, and subcutaneous interleukin-2.

Contact

Daniel Fowler, M.D. 301-402-3627
National Cancer Institute

Breast Cancer

Eligibility Requirements

Clinical stage II breast cancer; untreated except for biopsy of primary; good performance status.

Treatment/Procedures

Prospective randomization to receive chemotherapy with FLAC/G-CSF either preoperatively or postoperatively. Local therapy according to patient preference.

Contact

David N. Danforth, Jr., M.D. 301-496-1533
National Cancer Institute

Breast Cancer

Eligibility Requirements

Stage III_{A,B} breast cancer.

Treatment/Procedures

Patients with locally advanced (stage III_{A,B}) breast cancer will receive chemotherapy first, followed by local therapy (mastectomy and/or radiation therapy).

Contact

David N. Danforth, Jr., M.D. 301-496-1533
National Cancer Institute

Breast Cancer

Eligibility Requirements

Patients with breast cancer metastatic to distant sites who are HLA type A@ and whose tumors are HER2/neu (erb-2) positive; includes some patients with colon, ovarian, or prostate cancer.

Treatment/Procedures

Phase I vaccine trial; 4 subcutaneous injections at 3-week intervals; lymphocytophoresis procedures x 3.

Contact

David N. Danforth, Jr., M.D. 301-496-1533
National Cancer Institute

Breast Cancer

Eligibility Requirements

Patients with metastatic cancer whose tumors are HER2/neu (erbB-2) positive; includes some patients with breast, ovarian, prostate, and pancreatic cancers.

Treatment/Procedures

Specific antibody trial; immune therapy for the treatment of patients with HER2/neu, (erbB-2) positive tumors.

Contact

JoAnne Zujewski, M.D.
Kenneth H. Cowan, M.D., Ph.D. 301-496-4916
National Cancer Institute

Breast Cancer

Eligibility Requirements

Non-invasive breast cancer (ductal carcinoma in situ); lobular carcinoma in situ; very high risk family history.

Treatment/Procedures

Trial of tamoxifen and 4-HPR (vitamin A analog) in the prevention of breast cancer.

Contact

JoAnne Zujewski, M.D.
Kenneth H. Cowan, M.D., Ph.D. 301-496-4916
National Cancer Institute

Breast Cancer, High Risk

Eligibility Requirements

Women at high risk for breast cancer because of changes found on previous breast biopsy (LCIS, DCIS, atypical hyperplasia).

Treatment/Procedures

Patients receive chemopreventive drugs tamoxifen and retinoic acid; breast tissue examined.

Contact

David N. Danforth, Jr., M.D. 301-496-1533
National Cancer Institute

Breast Cancer, Education for BRCA1 Testing

Eligibility Requirements

Women 18 years old or older with one or more first degree relative(s) with breast cancer.

Treatment/Procedures

Education and counseling sessions on BRCA1 testing; randomization between interactive computer program and genetic counselor.

Contact

Barbara Biesecker, M.S. 301-496-3979
National Human Genome Research Institute

Breast Cancer, Hereditary

Eligibility Requirements

Previous enrollment in National Cancer Institute Genetics Epidemiology Branch studies; eligibility not open to individuals from high-risk cancer families.

Treatment/Procedures

BRCA2 testing offered following assessment of psychological variables and provision of an educational session; reasons for certain choices and their long-term consequences investigated.

Contact

Barbara Biesecker, M.S. 301-496-3979
National Human Genome Research Institute

Breast Cancer

Eligibility Requirements

Stage II, III or IV breast cancer.

Treatment/Procedures

High-dose sequential chemotherapy using blood stem cells.

Contact

JoAnne Zujewski, M.D. 301-496-4916

Kenneth H. Cowan, M.D., Ph.D.

National Cancer Institute

Breast Cancer

Eligibility Requirements

Stage II breast cancer.

Treatment/Procedures

High-dose sequential chemotherapy using blood stem cells genetically modified with the MDR (multidrug resistance) gene and the NeoR marking gene.

Contact

JoAnne Zujewski, M.D. 301-496-4916

Kenneth H. Cowan, M.D., Ph.D.

National Cancer Institute

Bullous Diseases, Autoimmune

Eligibility Requirements

Patients with adult-onset blistering disorders of the skin such as pemphigus foliaceus and vulgaris; paraneoplastic pemphigus; bullous pemphigoid; herpes gestationis; cicatricial pemphigoid; linear IgA disease; epidermolysis bullosa acquisita; etc.

Treatment/Procedures

Special diagnostic procedures such as direct and indirect immunofluorescence testing/immunoprecipitation studies; systemic glucocorticosteroids and glucocorticosteroid-sparing therapies.

Contact

Mark Udey, M.D.

Kim Yancey, M.D. 301-496-2681

National Cancer Institute

Candidiasis, Hepatosplenic

Eligibility Requirements

Cancer patients between 2 to 18 years old with evidence of hepatosplenic candidiasis that has progressed despite conventional therapy.

Treatment/Procedures

Evaluation of amphotericin B lipid complex (ABLC).

Contact

Attending Physician 301-402-0696
National Cancer Institute

Cervical Cancer

Eligibility Requirements

Patients 18 years of age or older; stage III/IV cervical cancer without infection or fistulae; HIV negative; CD4 counts \geq 200.

Treatment/Procedures

Human papilloma oncogene/vaccinia recombinant vaccine.

Contact

Barry L. Gause, M.D. 301-496-0901
National Cancer Institute

Colon Cancer, Familial

Eligibility Requirements

Patients 18 years of age or older; family history of colon cancer or polyps or presentation with diagnosis of colon cancer.

Treatment/Procedures

Education, counseling, and genetic testing.

Contact

Ilan R. Kirsch, M.D. 301-496-0901
Eileen Dimond, R.N., M.S. 301-435-5368
National Cancer Institute

Colon Cancer, Solid Tumors

See also *Immunotherapy/Vaccine*.

Colorectal Cancer

Eligibility Requirements

PS \leq 1; no prior therapy for metastatic disease; no history of seizure disorder or brain metastases; prior adjuvant therapy with 5-FU and leucovorin, levamisole, or alfa-interferon permitted only if more than six months have elapsed.

Treatment/Procedures

Outpatient.

Alfa-interferon	5mu/m ² /d	Days 1-6 SQ
Leucovorin	200mg/m ² /d	Days 2-6 IV over 30 min.
5-FU	370mg/m ² /d	Days 2-6 IV over 60 min.

Contact

Jean Grem, M.D. 301-496-0901
National Cancer Institute
Navy Medical Oncology Branch

Colorectal Cancer, Hereditary Non-Polyposis (Lynch Syndrome)

Eligibility Requirements

Patients 18 years of age and older, with colorectal cancer/polyps or a significant family history of colorectal cancer and/or endometrial, ovarian, or stomach cancer.

Treatment/Procedures

Individuals with colon cancer (and their first degree relatives) are asked to participate in education and counseling sessions regarding genetic testing for a specific hereditary form of colorectal cancer (Hereditary Non-Polyposis Colorectal Cancer [HNPCC], Lynch Syndrome). Genetic testing will be offered following the assessment of psychological variables, education and counseling sessions. Personal factors that affect individual decisions (beliefs, values, and experiences) will be studied.

Contact

Don Hadley, M.S. 301-496-3980
National Human Genome Research Institute

Colorectal Cancer, Hereditary Non-Polyposis (HNPCC)

Eligibility Requirements

Patients 18 years of age or older; HNPCC patient or HNPCC genetic mutation carrier.

Treatment/Procedures

Investigative colonoscopy. If eligible, receive oral chemopreventive agent or placebo.

Contact

Ilan Kirsch, M.D. 301-496-0901

Jean Jenkins, R.N., M.S.N., Ph.D. 301-496-0921

National Cancer Institute

Cutaneous Vasculitis

Eligibility Requirements

Patients with erythema elevatum diutinum; granuloma faciale; cutaneous leukocytoclastic vasculitis.

Treatment/Procedures

Diagnostic procedures as needed; Dapsone and other drug therapies.

Contact

Stephen I. Katz, M.D. 301-496-2681

National Cancer Institute

Dermatitis Herpetiformis

Eligibility Requirements

Patients with a gluten-sensitive blistering disorder, responsive to Dapsone.

Treatment/Procedures

Special diagnostic procedures such as direct and indirect immunofluorescence testing, diet, and drug therapy.

Contact

Stephen I. Katz, M.D. 301-496-2681

National Cancer Institute

Epidemiology: Tumors with unusual demographic or clinical features (unusual age of onset, bilaterality, multiple primary tumors, unusual pathology or response to therapy, or associated medical conditions)

Eligibility Requirements

Two or more affected cases (preferably living) among family members; verification of personal and possibly family medical history through questionnaires, interviews, and review of pathology slides; willingness to undergo phlebotomy.

Treatment/Procedures

No therapy beyond counseling offered but referral to other NCI clinical branches may be expedited; phlebotomy for genetic or molecular studies.

Contact

Referral Team 301-496-4375
National Cancer Institute

Epidemiology: Related to known or suspected risk factors (exposure to carcinogens such as ionizing radiation or chemotherapy, or genetic and congenital factors [birth defects, metabolic phenotype, chromosomal anomalies or Mendelian traits associated with tumors]).

Eligibility Requirements

Two or more affected cases (preferably living) among family members; verification of personal and possibly family medical history through questionnaires, interviews, and review of pathology slides; willingness to undergo phlebotomy.

Treatment/Procedures

No therapy beyond counseling offered, but referral to other NCI clinical branches may be expedited; phlebotomy for genetic or molecular studies.

Contact

Referral Team 301-496-4375
National Cancer Institute

Epidemiology: Familial cancers (bladder, breast [with or without ovarian], chordoma, testicular, lymphoproliferative [acute and chronic leukemias, Hodgkin's disease, non-Hodgkin's lymphoma], lung, melanoma, nevoid basal cell carcinoma syndrome, ovarian with or without breast cancer), Li-Fraumeni syndrome (childhood sarcomas, early onset breast cancer, brain tumors, leukemias among relatives), uterine

Familial Benign Neoplasms (Beckwith-Wiedemann Syndrome, meningiomas, neurofibromatosis type I, and neurofibromatosis type 2 [bilateral acoustic neurofibromatosis])

Eligibility Requirements

Two or more affected cases (preferably living) among family members.

Treatment/Procedures

No therapy beyond counseling offered, but referral to other NCI clinical branches may be expedited; verification of personal and family history through questionnaires, interviews, review of pathology slides. May involve blood drawing, skin biopsy, collection of other biologic specimens, and x-rays.

Contact

Referral Team 301-496-4375
National Cancer Institute

Ewing's Family of Tumors

Eligibility Requirements

Previously untreated patients or recurrent patients between 2 to 30 years of age.

Treatment/Procedures

Combination chemotherapy with cytokine administration and peptide vaccination.

Contact

Attending Physician 301-402-0696
National Cancer Institute

Growth Retardation

Eligibility Requirements

Selected patients between 4 and 20 years old who have growth retardation and laboratory evidence for resistance to insulin-like growth factor I (IGF-I).

Treatment/Procedures

Diagnostic evaluation of growth retardation and research studies of IGF-I resistance.

Contact

S. Peter Nissley, M.D. 301-496-6340
National Cancer Institute

Head and Neck Cancer

Eligibility Requirements

Patients with previously untreated stage III and IV squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx, nasopharynx, larynx, and maxillary sinus, as well as stage II squamous cell carcinoma of the base of tongue, nasopharynx and maxillary sinus.

Treatment/Procedures

External beam radiotherapy delivered concurrently with continuous IV infusion of paclitaxel delivered over 5 days, every 3 weeks.

Contact

Laurie Herscher, M.D. 301-496-5457
National Cancer Institute

Head and Neck Cancer

Eligibility Requirements

Patients with unresectable, locally advanced cancers of the head and neck, not previously treated with radiotherapy or chemotherapy.

Treatment/Procedures

Radiation response modifier gemcitabine administered concurrently with radiotherapy.

Contact

Laurie Herscher, M.D. 301-496-5457
National Cancer Institute

Head and Neck Cancer/Papilloma

Eligibility Requirements

Patients over the age of 18 with squamous cell carcinoma or papilloma of the upper aerodigestive tract who are candidates for standard or investigational therapy.

Treatment/Procedures

Treatment offered includes microlaryngoscopy, surgical excision, CO2 laser ablation and radiotherapy.

Contact

Carter Van Waes, M.D., Ph.D. 301-402-4216
National Institute on Deafness and Other Communication Disorders

HIV Infection, Childhood

Eligibility Requirements

Children 3 months to 18 years of age with either previously untreated HIV infection or with disease that has become intolerant or refractory to treatment.

Treatment/Procedures

Antiretroviral agents (e.g., reverse transcriptase inhibitors; protease inhibitors) alone or in combination; agents to improve host immunity (e.g., IL-2, interferon gamma, HIV vaccine).

Contact

Susan Sandelli, R.N. 301-402-1391
National Cancer Institute

HIV Infection, Symptomatic or AIDS

Eligibility Requirements

Children 3 months to 18 years of age with either previously untreated HIV infection or with disease that has become intolerant or refractory to treatment.

Treatment/Procedures

Antiretroviral agents (e.g., reverse transcriptase inhibitors; protease inhibitors) alone or in combination; agents to improve host immunity (e.g., IL-2, interferon gamma, HIV vaccine).

Contact

Susan Sandelli, R.N. 301-402-1391
National Cancer Institute

Hodgkin's and Non-Hodgkin's Lymphoma, Relapsed

Eligibility Requirements

Selected patients with all stages of relapsed disease.

Treatment/Procedures

Radiolabeled antibody directed against the alpha chain of the interleukin-2 receptor.

Contact

Jeffrey D. White, M.D. 301-402-2912
National Cancer Institute

Immunotherapy/Vaccine (Colon, Lung, Pancreatic, Prostate, and Thyroid Tumors)**Eligibility Requirements**

Diagnosis of solid tumors potentially expressing mutant ras in codon 12, to include colon, lung, pancreatic, prostate and thyroid; PS \leq 1; immune intact.

Treatment/Procedures

Escalating doses of ras peptides plus Detox™-adjuvant injected SQ repeated monthly \times 3; limited to patients whose tumor shows specific point mutation of ras.

Contact

Samir Khleif, M.D. 301-496-0901
National Cancer Institute

Immunotherapy/Vaccine (Prostate)**Eligibility Requirements**

Diagnosis of adenocarcinoma of the prostate; PSA ($>$ 3 ng/ml; PS \leq 2; AGC $>$ 2,000; platelets $>$ 100,000; Hb $>$ 8.0 grams/dl; bili $<$ 1.6 mg/dl; AST and ALT $<$ 4 \times normal; creatinine $<$ 1.6 mg/dl.

Treatment/Procedures

Escalating doses of recombinant vaccinia virus that expresses PSA given monthly \times 3.

Contact

Alice Chen, M.D. 301-496-0901
National Cancer Institute

Immunotherapy/Vaccine**Eligibility Requirements**

Diagnosis of any solid tumor exhibiting ras or p53 mutations, to include lung, colon, breast, ovarian, head and neck, pancreatic, esophageal, and gastric; PS \leq 1; AST (SGOT) \leq 2.0 \times ULN; bili \leq 1.5; creatinine \leq 2.0.

Treatment/Procedures

Infusion of patient's own antigen presenting blood cells after incubation with tumor specific mutated peptides of p53 or ras; patients will first enter the tissue evaluation portion of the trial; identification of a ras or p53 mutation and generation of a tumor specific peptide may take 1 to 6 months.

Contact

Michael Kelley, M.D. 301-496-0929
Bruce Johnson, M.D. 301-496-0901
National Cancer Institute

Immunotherapy, Vaccine (Breast, Lung, Colon, Pancreatic, Ovary, Thyroid, Head and Neck, Esophageal, and Gastric Tumors)

Eligibility Requirements

PS \leq 1; AST \leq 2.0; bili \leq 2.0; creatinine \leq 2.0; any solid tumor including breast, lung, colon, pancreatic, ovary, thyroid, head and neck, esophageal and gastric.

Treatment/Procedures

Vaccination with peptides that correspond to the patient's p53 or ras genetic mutation; expanding patient's peptide-activated lymphocytes (PAL) along with SQ IL2.

Contact

Samir Khleif, M.D. 301-496-0901
National Cancer Institute

Immunotherapy, Vaccine (Squamous Cell Carcinoma of Cervix)

Eligibility Requirements

Histologic diagnosis of squamous cell carcinoma of the cervix; stage III, IV or recurrent disease; PS \leq 1; patient should be HLA-A2.1 subtype; creatinine $<$ 2.0 mg/dl; bili $<$ 2 mg/dl; SGPT $<$ 4 \times normal.

Treatment/Procedures

Patient treated with HPV 16 E6 or E7 peptide pulsed on the patient's peripheral blood cells; total of 4 vaccinations.

Contact

Samir Khleif, M.D. 301-496-0901
National Cancer Institute

Kaposi's Sarcoma

Eligibility Requirements

HIV-infected patients with Kaposi's sarcoma that is not immediately life threatening.

Treatment/Procedures

Oral therapy with thalidomide, which has anti-angiogenesis activity in animal models.

Contact

Robert Yarchoan, M.D.
Jill Lietzau, R.N. 301-496-8959
National Cancer Institute

Kaposi's Sarcoma

Eligibility Requirements

HIV-infected patients with Kaposi's sarcoma.

Treatment/Procedures

Subcutaneous therapy with interleukin-12 (IL-12) for its possible anti-Kaposi's and its immunostimulatory activities.

Contact

Robert Yarchoan, M.D.
Jill Lietzau, R.N. 301-496-8959
National Cancer Institute

Kaposi's Sarcoma

Eligibility Requirements

Patients with Kaposi's sarcoma and at least 50 CD4 cells/mm³.

Treatment/Procedures

Treatment with cidofovir, a new anti-herpes drug, for its possible activity against Kaposi's sarcoma-associated herpes virus.

Contact

Robert Yarchoan, M.D.
Jill Lietzau, R.N. 301-496-8959
National Cancer Institute

Kidney Cancer

See also *Renal Cell, Metastatic*.

Kidney Cancer

Eligibility Requirements

Familial kidney cancer; Von Hippel-Lindau disease.

Treatment/Procedures

Clinical evaluation for presence of familial kidney cancer; selected patients eligible for surgery for kidney, adrenal, pancreatic, CNS, or other manifestations of VHL or other hereditary kidney cancer.

Contact

W. Marston Linehan, M.D. 301-496-6353
National Cancer Institute

Kidney Cancer, Hereditary/Familial

Eligibility Requirements

Von Hippel-Lindau disease; any family at risk for hereditary kidney cancer; i.e., with two or more members affected with papillary or other form of kidney cancer.

Treatment/Procedures

Clinical evaluation for presence of familial kidney cancer; selected patients eligible for surgery for kidney, adrenal, pancreatic, CNS or other manifestations of VHL or other hereditary kidney cancer.

Contact

W. Marston Linehan, M.D. 301-496-6353
National Cancer Institute

Leukemia, Adult T-cell

Eligibility Requirements

Selected patients with human T-cell lymphotropic virus-I-associated (HTLV-I) adult T-cell leukemia.

Treatment/Procedures

Admitted for study and immunotherapy with monoclonal antibodies.

Contact

Jeffrey D. White, M.D. 301-402-2912
National Cancer Institute

Leukemia, Hairy Cell or Large Granular Lymphocytic

Eligibility Requirements

Patients with hairy cell or large granular lymphocytic leukemia.

Treatment/Procedures

Purine analogue therapy.

Contact

Barry L. Gause, M.D. 301-846-1520
National Cancer Institute

Leukemia, T-cell Type Large Granular Lymphocytic

Eligibility Requirements

Selected patients with T-cell type LGL leukemia associated with granulocytopenia or thrombocytopenia.

Treatment/Procedures

Admitted for study and immunotherapy with monoclonal antibodies.

Contact

Jeffrey D. White, M.D. 301-402-2912
National Cancer Institute

Leukemia, Lymphoblastic

Eligibility Requirements

Previously untreated patients between 1 to 20 years of age in either average- or high-risk category.

Treatment/Procedures

Combination chemotherapy with cytokine therapy.

Contact

Attending Physician 301-402-0696
National Cancer Institute

Liver Cancer, Metastatic and Primary

Eligibility Requirements

Histologically proven unresectable primary or metastatic disease confined to the parenchyma of the liver; ECOG performance of 0 or 1; adequate hepatic function as evidenced by bilirubin less than 2.0 mg/dL and normal PT/PTT; patients excluded who have biopsy-proven cirrhosis, evidence of significant portal hypertension, compromised cardiopulmonary function, or abnormal hematologic profile.

Treatment/Procedures

One-hour hyperthermic isolated hepatic perfusion administered via a laparotomy using escalating dose melphalan.

Contact

H. Richard Alexander, M.D. 301-496-5049
National Cancer Institute

Lung Cancer, Non-Small Cell

Eligibility Requirements

Extensive SCLC or stage II-IV NSCLC; no prior therapy; PS \leq 2; no significant cardiac history; AGC \geq 1,200; platelets \geq 100,000; bili \leq 1.5; creatinine \leq 1.5 mg/dl.

Treatment/Procedures

Paclitaxel 96-hour (4-day) infusion on days 1 to 5; starting dose 25 mg/m²/day; cisplatin 60 mg/m² on day 5 after completion of paclitaxel infusion; cycles repeated every 3 weeks.

Contact

Bruce Johnson, M.D. 301-496-0901
Oscar Breathnach, M.D. 301-435-5462
Vijay Kasturi, M.D. 301-435-5405
National Cancer Institute

Lung Cancer, Non-Small Cell

Eligibility Requirements

Previously untreated patients with non-small cell lung cancer; PS \leq 1; adequate hematologic, renal, and hepatic function.

Treatment/Procedures

Paclitaxel 30 mg/m² daily via continuous infusion for 4 days followed by cisplatin 80 mg/m² as an IV bolus.

Contact

Bruce Johnson, M.D. 301-496-0901
Oscar Breathnach, M.D. 301-435-5462
Vijay Kasturi, M.D. 301-435-5405
National Cancer Institute

Lung Cancer, Oat Cell

Eligibility Requirements

Extensive stage small cell lung cancer with intrathoracic relapse.

Treatment/Procedures

Hyperfractionated low dose rate chest radiotherapy; study performed in conjunction with NCI-Navy.

Contact

Laurie Herscher, M.D. 301-496-5457
National Cancer Institute

Lung Cancer, Small Cell

Eligibility Requirements

PS \leq 2; SCLC with chest relapse; no prior chest XRT.

Treatment/Procedures

Radiotherapy twice per day (at least 4 hours between fractions) in 150 rad fractions for total of 300 rads per day, using opposing field techniques; rate delivery no more than 5 rad per minute; therapy given over three weeks for planned total dose of 4500 rads at midplane.

Contact

Bruce Johnson, M.D. 301-496-0901
 Vijay Kasturi, M.D. 301-435-5405
 National Cancer Institute

Lung Cancer, Solid Tumors

See *Immunotherapy/Vaccine*.

Lymphoma

Eligibility Requirements

Patients 18 years old or older with previously treated indolent, intermediate, or high-grade non-Hodgkin's lymphoma.

Treatment/Procedures

Monoclonal antibody conjugated with toxin plus cytokine.

Contact

Jon T. Holmlund, M.D. 301-846-1520
 National Cancer Institute

Lymphoma

Eligibility Requirements

Previously untreated patients with stage III or IV follicular B-cell lymphoma.

Treatment/Procedures

Chemotherapy and immunoglobulin idiotype antigen vaccine.

Contact

Larry W. Kwak, M.D., Ph.D.
 Thelma Watson, R.N. 301-435-5608
 National Cancer Institute

Lymphomas, Cutaneous T-cell (Sezary syndrome) Mycosis Fungoides

Eligibility Requirements

Selected patients with cutaneous T-cell lymphomas.

Treatment/Procedures

Admitted for study and immunotherapy with monoclonal antibodies.

Contact

Jeffrey D. White, M.D. 301-402-2912
National Cancer Institute

Lymphoma/Leukemia

Eligibility Requirements

Patients with T-cell leukemia/lymphoma/lymphoproliferative disorders who have failed or refused previous standard therapies. Patients must be 18 years of age and without active infection.

Treatment/Procedures

Monoclonal antibody.

Contact

Mario Sznol, M.D. 301-846-1520
National Cancer Institute

Lymphomas Pediatric (small non-cleaved, diffuse large cell and lymphoblastic)

Eligibility Requirements

Previously untreated patients up to 24 years of age.

Treatment/Procedures

Combination chemotherapy with cytokine therapy.

Contact

Attending Physician 301-402-0696
National Cancer Institute

Lymphomatoid Granulomatosis

Eligibility Requirements

Previously treated and untreated patients with grade I, II and III LYG.

Treatment/Procedures

Interferon or EPOCH chemotherapy.

Contact

Wyndham H. Wilson, M.D., Ph.D. 301-435-2415
National Cancer Institute

Melanoma

Eligibility Requirements

Stage III or IV disease without CNS involvement; patients must be HLA A1 or A2 positive.

Treatment/Procedures

Allogeneic vaccine.

Contact

Barry L. Gause, M.D. 301-496-0901
National Cancer Institute

Melanoma

Eligibility Requirements

Patients 18 years old or older with recurrent or metastatic melanoma with ≥ 3 cutaneous or subcutaneous nodules; patients must be without CNS involvement and HLA A1 or A2.

Treatment/Procedures

Phenylacetate.

Contact

Barry L. Gause, M.D. 301-496-0901
National Cancer Institute

Melanoma, Malignant Metastatic

Eligibility Requirements

Measurable disease with HAL type A1, A2, A3, A24, or A31; no prior treatment within 30 days; no steroid requirements; life expectancy greater than 12 weeks with good performance status.

Treatment/Procedures

Phase I vaccine; 4 subcutaneous injections at 3 week intervals; lymphocytapheresis procedures $\times 3$. Potential for treatment with combination peptides and IL-2 or GMCSF.

Contact

David N. Danforth, M.D. 301-496-1533
National Cancer Institute

Metabolic Phenotype

See *Cancer, Epidemiology*.

Metastatic Cancer

Eligibility Requirements

Patients with metastatic or advanced cancer with breast, ovarian and sarcoma.

Treatment/Procedures

Paclitaxel (given by continuous intravenous infusion) plus PSC 833 (given orally), a cyclosporine analogue and P-glycoprotein antagonist; phase I study.

Contact

Susan E. Bates, M.D. 301-402-0984
National Cancer Institute

Non-Hodgkin's Lymphoma, HIV-related

Eligibility Requirements

All stages of previously untreated HIV-related lymphomas; relapse after one regimen.

Treatment/Procedures

EPOCH chemotherapy; Interleukin-12.

Contact

Wyndham H. Wilson, M.D., Ph.D. 301-435-2415
National Cancer Institute

Non-Hodgkin's Lymphoma, HIV-related

Eligibility Requirements

All stages previously untreated HIV-related lymphomas.

Treatment/Procedures

EPOCH chemotherapy.

Contact

Wyndham H. Wilson, M.D., Ph.D. 301-435-2415
National Cancer Institute

Non-Hodgkin's Lymphoma, Intermediate-grade

Eligibility Requirements

Previously untreated grades II, III and IV.

Treatment/Procedures

EPOCH chemotherapy (dose-escalating).

Contact

Wyndham H. Wilson, M.D., Ph.D. 301-435-2415
National Cancer Institute

Non-Hodgkin's Lymphoma and Solid Tumors

Eligibility Requirements

Solid tumors and non-Hodgkin's lymphoma; good end organ function.

Treatment/Procedures

Treatment with orally available cytostatic, antiangiogenic, signal transduction inhibitor (CAI).

Contact

Ovarian Cancer Team, Drs. Reed, Kohn, Sarosy 301-402-1357
National Cancer Institute

Non-Hodgkin's Lymphoma and Solid Tumors

Eligibility Requirements

Solid tumors and non-Hodgkin's lymphoma; good end organ function.

Treatment/Procedures

Treatment with orally available cytostatic, antiangiogenic, signal transduction inhibitor (CAI), in combination with paclitaxel (Taxol®).

Contact

Ovarian Cancer Team, Drs. Reed, Kohn, Sarosy 301-402-1357
National Cancer Institute

Osteosarcoma

Eligibility Requirements

Previously treated patients up to age 25 with evidence of refractory disease.

Treatment/Procedures

Phase I/II therapy.

Contact

Attending Physician 301-402-0696
National Cancer Institute

Osteosarcoma

Eligibility Requirements

Patients 30 years of age or younger; no prior therapy; high-grade osteosarcoma confirmed to extremity and no evidence of metastases.

Treatment/Procedures

Randomized presurgical chemotherapy followed by surgery and adjuvant chemotherapy.

Contact

Allen Goorin, M.D. 617-735-7318
Dana Farber Cancer Institute

Ovarian Cancer

Eligibility Requirements

Biopsy proven recurrent epithelial ovarian cancer that has failed standard effective therapy including cisplatin/carboplatin or paclitaxel containing regimens. Good performance status.

Treatment/Procedures

Adoptive immunotherapy with gene-modified lymphocytes and high dose interleukin-2; necessary procedures include lymphocytapheresis and fine needle aspirations of tumor.

Contact

Patrick Hwu, M.D. 301-402-1156
National Cancer Institute

Ovarian Cancer, Hereditary

Eligibility Requirements

Previous enrollment in National Cancer Institute Genetics Epidemiology Branch studies; eligibility not open to individuals from high-risk cancer families.

Treatment/Procedures

BRCA1 testing offered following assessment of psychological variables and provision of an educational session; reasons for certain choices and their long-term consequences are under investigation.

Contact

Barbara Biesecker, M.S. 301-496-3979
National Human Genome Research Institute

Ovarian Cancer, Newly Diagnosed, Advanced Stage

Eligibility Requirements

Newly diagnosed stage IIC-IV epithelial ovarian cancer.

Treatment/Procedures

Dose intense paclitaxel (Taxol®) with cyclophosphamide and cisplatin chemotherapy with granulocyte colony-stimulating factor support.

Contact

Ovarian Cancer Team, Drs. Reed, Kohn, Sarosy 301-402-1357
National Cancer Institute

Ovarian Cancer, Relapsed or Refractory

Eligibility Requirements

Relapsed or refractory epithelial ovarian cancer.

Treatment/Procedures

9-mainocamptothecin chemotherapy with granulocyte colony-stimulating factor support.

Contact

Ovarian Cancer Team, Drs. Reed, Kohn, Sarosy 301-402-1357
National Cancer Institute

Ovarian Cancer, Solid Tumors

See also *Immunotherapy/Vaccine*.

Pancreas Cancer

Eligibility Requirements

Patients with locally advanced or locally recurrent pancreatic carcinoma.

Treatment/Procedures

Radiotherapy delivered concurrently with gemcitabine; gemcitabine administered as a 24-hour infusion on first day of irradiation then weekly for total of 5 doses.

Contact

Laurie Herscher, M.D. 301-496-5457
National Cancer Institute

Pancreas Cancer, Solid Tumors

See *Immunotherapy/Vaccine*.

Pediatric Cancers of Childhood, Relapsed

Eligibility Requirements

Previously treated patients between 1-24 years of age with evidence of refractory disease.

Treatment/Procedures

Phase I/II disease.

Contact

Attending Physician 301-402-0696
National Cancer Institute

Peritoneal Carcinomatosis

Eligibility Requirements

Patients with histologically proven peritoneal carcinomatosis from any histology that has failed standard therapy; ECOG performance status of 0 or 1; adequate renal function as evidenced by serum creatinines ≤ 2.0 mg/dL; adequate cardiopulmonary function.

Treatment/Procedures

Ninety-minute continuous hyperthermic peritoneal perfusion with escalating dose cisplatin administered via exploratory laparotomy after maximal tumor debulking.

Contact

H. Richard Alexander, M.D. 301-496-5049
National Cancer Institute

Pharyngeal Cancer

See Head and Neck Cancer, Aerodigestive Tract.

Pityriasis Rosea

Eligibility Requirements

Patients previously seen by a dermatologist and diagnosed with pityriasis rosea.

Treatment/Procedures

Three percent cidofovir cream and procedures to determine possible herpesviral etiology.

Contact

Andrew Blauvelt, M.D. 301-402-4167
National Cancer Institute

Prostate Cancer

Eligibility Requirements

Localized prostate cancer.

Treatment/Procedures

Radical prostatectomy.

Contact

W. Marston Linehan, M.D. 301-496-6353
National Cancer Institute

Prostate Cancer

Eligibility Requirements

Familial prostate cancer.

Treatment/Procedures

Clinical evaluation of affected individual and at risk family members; selected patients eligible for radical prostatectomy.

Contact

W. Marston Linehan, M.D. 301-496-6353
National Cancer Institute

Prostate Cancer

Eligibility Requirements

Newly diagnosed, androgen-independent prostate cancer.

Treatment/Procedures

Thalidomide.

Contact

William D. Figg, Pharm.D. 301-402-3622 or 402-8606
National Cancer Institute

Prostate Cancer

Eligibility Requirements

Patients with prostate cancer.

Treatment/Procedures

Phase II trial of CAI in androgen-independent prostate cancer. Daily oral treatment.

Contact

William D. Figg, Pharm.D. 301-401-3622 or 301-402-8606
National Cancer Institute

Prostate Cancer, Solid Tumors

See *Immunotherapy/Vaccine*.

Radiation, Late Effects

Eligibility Requirements

Patients with late fibrovascular sequelae of radiation therapy with quantifiable symptomatology or disability.

Treatment/Procedures

Pentoxifylline administered orally over 8-week period; serial clinical and laboratory evaluations made before treatment, during treatment, and after treatment.

Contact

Rosemary Altemus, Ph.D., M.D. 301-496-5457
National Cancer Institute

Renal Cancer

See *Cancer, Metastatic*.

Renal Cell, Metastatic

Eligibility Requirements

Measurable disease with primary tumor either resected or found to be unresectable; primary tumor may be resected at NCI (see cancer, renal cell primary); no CNS involvement or cardiovascular impairment; good performance status; no prior IL-2 therapy; no steroid requirements; no other treatment within 30 days.

Treatment/Procedures

Randomization into 3-arm trial to receive high-dose IV IL-2, low doses IV IL-2 or subcutaneous IL-2 as an outpatient.

Contact

W. Marston Linehan, M.D. 301-496-6353
David N. Danforth, M.D. 301-496-1533
National Cancer Institute

Rhabdomyosarcoma

Eligibility Requirements

Previously untreated patients between 1-24 years of age with Stage II-IV disease.

Treatment/Procedures

Combination chemotherapy with cytokine administration and peptide vaccination.

Contact

Attending Physician 301-402-0696
National Cancer Institute

Sarcoma, Adult Soft Tissue

Eligibility Requirements

Patients with non-metastatic stage 2 or 3 (high-grade) soft tissue sarcoma of the extremities.

Treatment/Procedures

Surgery and randomization to adjuvant chemotherapy.

Contact

James C. Yang, M.D. 301-496-1574
National Cancer Institute

Sarcoma, Adult Soft Tissue

Eligibility Requirements

Patients with stage 1 (low-grade) soft tissue sarcoma.

Treatment/Procedures

Surgery with randomization to adjuvant post-operative radiotherapy.

Contact

James C. Yang, M.D. 301-496-1574
National Cancer Institute

Sarcoma, Unresectable Extremity

Eligibility Requirements

Histologically proven primary or recurrent unresectable extremity sarcoma with or without distant metastases. Patients must have a life expectancy of greater than 6 months; ECOG performance status of 0 or 1; no evidence of severe peripheral vascular occlusive disease; platelet count of $> 150,000$; normal coagulation studies; bilirubin of < 1.5 mg/dL; creatinine of < 2.0 mg/dL.

Treatment/Procedures

Ninety-minute hyperthermic isolated limb perfusion with melphalan and tumor necrosis factor.

Contact

H. Richard Alexander, M.D. 301-496-5049
National Cancer Institute

Skin Cancer, Disorders of Cornification

Eligibility Requirements

Selected patients with basal cell carcinoma or squamous cell carcinoma (especially the nevoid basal cell carcinoma syndrome and xeroderma pigmentosum), disorders of cornification (the ichthyoses, Darier's disease), or psoriasis may be eligible for study.

Treatment/Procedures

Skin biopsy; research bloods drawn; experimental treatments.

Contact

John J. DiGiovanna, M.D. 301-402-1607
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Solid Tumors

Eligibility Requirements

PS \leq 2; ACG $>$ 2000; T. bili \leq 1.6; SGOT \leq 140; creatinine \leq 1.6.

Treatment/Procedures

9-AC schedule: q 14 days, 72 hr. infusion; starting dose level: 25 mcg/m²/hr; dose escalation: 25, 35, 47, 59 & 72 mcg/m²/hr.; outpatient; central line required.

Contact

Jean Grem, M.D. 301-496-0901
National Cancer Institute

Solid Tumors

Eligibility Requirements

PS $<$ 2; ACG $>$ 2,000; T. bili $<$ 1.8; SGOT $<$ 140; creatinine $<$ 1.7.

Treatment/Procedures

Present dose level: 16.7 mcg/m²/hr. outpatient.

9-AC Schedule: Level 1	1.5	week infusion	(Mon-Fri)
Level 2	2	week infusion	" "
Level 3	2.5	week infusion	" "
Level 4	3	week infusion	" "

Contact

Jean Grem, M.D. 301-496-0901
National Cancer Institute

Solid Tumors

Eligibility Requirements

Patients who have failed all effective therapies for their disease; PS \leq 2; AGC \geq 2000/ μ l; platelets \geq 100,000/ μ l; bilirubin \leq 2.0 mg/dl; creatinine \leq 2.0 mg/dl; HIV negative; no primary CNS malignancy or CNS metastases.

Treatment/Procedures

This Phase I protocol seeks to determine toxicities associated with administration of a fixed dose of gemcitabine as a 24-hour continuous IV infusion followed by 5-fluoro-2'-deoxyuridine (FUdR) administered by continuous infusion over 24 to 96 hours (starting immediately after the completion of the dFdC infusion); treatment repeated weekly for three weeks out of four; low dose oral leucovorin (LV) given starting the day prior to FUdR and then each day FUdR is given; dose escalation of FUdR initially proceeds by increasing duration of FUdR infusion; depending on type of clinical toxicities experienced for given duration of FUdR infusion, dose of FUdR may then be escalated in subsequent cohorts of patients until dose-limiting toxicity is seen.

Contact

Jean Grem, M.D. 301-496-0901
Mark Georgiadis, LCDR, MC, USN 301-295-1159
National Cancer Institute

Solid Tumors

Eligibility Requirements

PS \leq 2; AGC $>$ 1500/ μ l; platelets $>$ 100,000 μ /l; bili \leq 2.0 md/dl; HIV negative; no CNS malignancies. Indwelling central venous catheter required.

Treatment/Procedures

Irinotecan administered by continuous venous infusion at initial dose of 10 mg/m²/d for 96 hours, alternating with 72-hour drug-free intervals; duration of these treatments escalated in cohorts of new patients until patients are receiving therapy for 3 out of every 4 weeks.

Contact

Chris Takimoto, M.D. 301-496-0901
National Cancer Institute

Solid Tumors

Eligibility Requirements

Age \geq 18 years old; ECOG PS \leq 2; AGC \geq 2000/ μ L; platelets \geq 100,000/ μ L; bilirubin \leq 1.6 mg/dL; creatinine \leq 1.6 mg/dL; HIV negative; no primary CNS malignancy or CNS metastases.

Treatment/Procedures

This Phase I protocol seeks to determine toxicities associated with administration of pyrazoloacridine (PZA) as a 24-hour continuous IV infusion weekly for three weeks, followed by a one-week rest; dose escalation will proceed in 50% increments until grade 1 clinical toxicity (excluding nausea and vomiting) is seen; thereafter, dose escalation will proceed in 25% increments until dose-limiting toxicity occurs in two of three patients at a given dose level.

Contact

Jean Grem, M.D. 301-496-0901
National Cancer Institute

Solid Tumors, Refractory

Eligibility Requirements

Patients with refractory solid tumors.

Treatment/Procedures

Phase I trial of COL-3. Daily oral treatment of a matrix metalloproteinase inhibitor.

Contact

William D. Figg, Pharm.D. 301-402-3622 or 301-402-8606
National Cancer Institute

Solid Tumors and Non-Hodgkin's Lymphoma

Eligibility Requirements

Solid tumors and non-Hodgkin's lymphoma; good end organ function.

Treatment/Procedures

Treatment with orally available cytostatic, antiangiogenic, signal transduction inhibitor (CAI).

Contact

Ovarian Cancer Team, Drs. Reed, Kohn, Sarosy 301-402-1357
National Cancer Institute

Solid Tumors and Non-Hodgkin's Lymphoma

Eligibility Requirements

Solid tumors and non-Hodgkin's lymphoma; good end organ function.

Treatment/Procedures

Treatment with orally available cytostatic, antiangiogenic, signal transduction inhibitor (CAI) in combination with paclitaxel (Taxol®).

Contact

Ovarian Cancer Team, Drs. Reed, Kohn, Sarosy 301-402-1357
National Cancer Institute

Thyroid Neoplasms

Eligibility Requirements

Adult patients with thyroid nodules or thyroid cancer.

Treatment/Procedures

Medical evaluation to include fine needle aspiration and possible surgery; the use of ¹³¹I for diagnostic scanning and therapy. Studies of recombinant TSH in the management of thyroid cancer are ongoing.

Contact

Monica Skarulis, M.D. 301-496-1913
National Institute of Diabetes and Digestive and Kidney Diseases

Tropical Spastic Paraparesis

Eligibility Requirements

Selected patients with tropical spastic paraparesis (TSP).

Treatment/Procedures

Admitted for study and immunotherapy with monoclonal antibodies.

Contact

Thomas A. Waldmann, M.D. 301-496-6653
National Cancer Institute

Cardiovascular Diseases

Angina, Microvascular; Sensitive Heart Syndrome

Eligibility Requirements

Patients with angina-like chest pain despite normal coronary angiograms.

Treatment/Procedures

Assessment of inducible myocardial ischemia using stress nuclear and echocardiographic techniques and investigation of coronary vascular dynamics. Assessment of cardiac pain sensitivity made during cardiac catheterization.

Contact

Richard O. Cannon III, M.D. 301-496-9895
National Heart, Lung, and Blood Institute

Coronary Artery Disease

Eligibility Requirements

Patients with known or suspected coronary artery disease, or chest pain syndrome.

Treatment/Procedures

Diagnosis and evaluation of coronary artery disease by non-invasive stress testing including exercise testing, radionuclide imaging including positron emission tomography and cardiac catheterization. Eligible patients will be provided coronary bypass surgery or angioplasty as deemed necessary.

Contact

Arshed A. Quyyumi, M.D. 301-496-0022
National Heart, Lung, and Blood Institute

Hyperaldosteronism

Eligibility Requirements

Patients 18 to 70 years of age with primary aldosteronism, dexamethasone-suppressible aldosteronism, Liddle syndrome, and other disorders of apparent mineralocorticoid excess.

Treatment/Procedures

Full diagnostic workup and localization studies which include bilateral adrenal vein catheterization and medical treatment or surgical removal, as indicated and desired.

Contact

John R. Gill, M.D. 301-496-6268
National Heart, Lung, and Blood Institute

Hyperlipidemia (Hypercholesterolemia/Hypertriglyceridemia)

Eligibility Requirements

Patients with elevated plasma cholesterol or triglyceride levels.

Treatment/Procedures

Diagnosis and evaluation of the hyperlipidemia by analysis of plasma lipoproteins, apolipoproteins, enzyme assays, and selective determination of specific gene sequences as required for complete elucidation of the lipoprotein profile and the genetic diagnosis.

Contact

H. Bryan Brewer, Jr., M.D. 301-496-1500
National Heart, Lung, and Blood Institute

Hypertension, Essential

Eligibility Requirements

Patients under 55 years old without advanced degenerative changes.

Treatment/Procedures

Therapy with new and/or standard pharmacologic agents and regimens. Diagnostic workup as appropriate.

Contact

Harry R. Keiser, M.D. 301-496-1518
National Heart, Lung, and Blood Institute

Hypertension, Familial

Eligibility Requirements

Patients with the following types of familial hypertension: ACTH-dependent (Laidlaw); low-renin, low-aldosterone (Liddle); DOCA-dependent with 11-hydroxylase deficiency (adrenogenital) or without (Biglieri).

Treatment/Procedures

Therapy with new pharmacologic agents and regimens.

Contact

Harry R. Keiser, M.D. 301-496-1518
National Heart, Lung, and Blood Institute

Hypolipidemia (Low plasma cholesterol or HDL cholesterol)

Eligibility Requirements

Patients with low plasma levels of total cholesterol or HDL cholesterol.

Treatment/Procedures

Diagnosis and evaluation of the hypolipoproteinemia by analysis of plasma lipoproteins, apolipoproteins, cholesterol transfer and enzyme assays, and selective determination of specific gene sequences as required for complete elucidation of the lipoprotein profile.

Contact

H. Bryan Brewer, Jr., M.D. 301-496-1500
National Heart, Lung, and Blood Institute

Pheochromocytoma/Paraganglioma

Eligibility Requirements

Subjects of any age with hypertension and biochemical evidence suggestive of catecholamine excess.

Treatment/Procedures

Full diagnostic workup, including tests of blood and urine for catecholamines and their metabolites, plus clonidine suppression and glucagon stimulation tests. CT, MRI and radioactive MIBG scans as indicated. Surgical removal, if appropriate and desired.

Contact

Harry R. Keiser, M.D. 301-496-1518
National Heart, Lung, and Blood Institute

Valvular Heart Disease

Eligibility Requirements

Patients with aortic or mitral valvular regurgitation.

Treatment/Procedures

Investigation to determine the optimal time for operative intervention. Studies to determine those (echocardiographic, radionuclide, hemodynamic) measurements that most reliably reflect reversible or irreversible myocardial dysfunction.

Contact

Julio A. Panza, M.D. 301-496-2634
National Heart, Lung, and Blood Institute

Deafness and Communication Disorders

Head and Neck Cancer/Papilloma

Eligibility Requirements

Patients over the age of 18 with squamous cell carcinoma or papilloma of the upper aerodigestive tract who are candidates for standard or investigational therapy.

Treatment/Procedures

Treatment offered includes microlaryngoscopy, surgical excision, CO2 laser ablation and radiotherapy.

Contact

Carter Van Waes, M.D., Ph.D. 301-402-4216
National Institute on Deafness and Other Communication Disorders

Hearing Children of Deaf Parents

Eligibility Requirements

Patients between the ages of 18 and 80 who are the hearing offspring of deaf adults; American Sign Language acquired in childhood.

Treatment/Procedures

Neurological evaluation; PET scan; MRI scan.

Contact

Allen R. Braun, M.D. 301-402-1497
National Institute on Deafness and Other Communication Disorders

Hearing Impairment (Deafness)

Eligibility Requirements

Subjects between the ages of 18 and 80 with profound hearing impairment, congenital or acquired; fluent in American Sign Language.

Treatment/Procedures

Neurological evaluation; MRI scan.

Contact

Allen R. Braun, M.D. 301-402-1497
National Institute on Deafness and Other Communication Disorders

Hearing Impairment (Hereditary)

Eligibility Requirements

Families with nonsyndromic and syndromic hearing impairment ages 1 to 65.

Treatment/Procedures

Audiology assessment, physical examination, blood samples, buccal swabs, genetic linkage studies.

Contact

Thomas Friedman, Ph.D. 301-496-7882

National Institute on Deafness and Other Communication Disorders

Hearing, Normal Volunteers

Eligibility Requirements

Healthy subjects between the ages of 18 and 80; no major medical illnesses; not on psychoactive medications.

Treatment/Procedures

Neurological evaluation; PET scan; MRI scan.

Contact

Allen R. Braun, M.D. 301-402-1497

National Institute on Deafness and Other Communication Disorders

Otitis Media (Middle Ear Infection) Vaccine, Healthy Volunteers

Eligibility Requirements

Healthy volunteers between the ages of 18 to 35 years.

Treatment/Procedures

Blood draws, history and physicals.

Contact

Xin-King Gu, M.D. 301-402-4214

National Institute on Deafness and Other Communication Disorders

Overexposure to Noise, Healthy Volunteers

Eligibility Requirements

18 to 25 year olds with good health, normal hearing, and no family history of hearing loss.

Treatment/Procedures

Exposure to 10 minutes of moderately loud noise. Hearing testing, no invasive procedures.

Contact

Lawrence Shotland, Ph.D. 301-496-5368

National Institute on Deafness and Other Communication Disorders

Parkinson's Disease

Eligibility Requirements

Patients 18 to 80 years old with Parkinson's disease or related disorders with Parkinsonian features.

Treatment/Procedures

Neurological evaluation; PET scan; MRI scan.

Contact

Allen R. Braun, M.D. 301-402-1497

National Institute on Deafness and Other Communication Disorders

Spasmodic Dysphonia

Eligibility Requirements

Patients 18 to 80 years old with adductor or abductor spasmodic dysphonia.

Treatment/Procedures

Neurological evaluation; PET scan; MRI scan.

Contact

Allen R. Braun, M.D. 301-402-1497

National Institute on Deafness and Other Communication Disorders

Speech Disorders

Eligibility Requirements

Persons between the ages of 5 and 75 years from families with speech disorders and also persons previously diagnosed with stuttering and/or cluttering.

Treatment/Procedures

Complete diagnostic testing of affected and unaffected family members is used to determine the type of disorder and the recommended treatment approach. Blood draw or buccal swab.

Contact

Christy Ludlow, Ph.D. 301-496-9365

National Institute on Deafness and Other Communication Disorders

Stuttering

Eligibility Requirements

People between the ages of 18 and 80 who stutter; dysfluency may be developmental (onset during childhood) or acquired (onset as an adult).

Treatment/Procedures

Neurological evaluation; PET scan; MRI scan.

Contact

Allen R. Braun, M.D. 301-402-1497

National Institute on Deafness and Other Communication Disorders

Stuttering (Gene Mapping and Genetic Analysis)

Eligibility Requirements

Age range is from 5 to 90 years. Persons who stutter and who have a large number of persons who stutter in their family (across two to three generations) will be evaluated as well as unaffected family members.

Treatment/Procedures

Blood draw, buccal swab, finger stick and speech testing.

Contact

Allen R. Braun, M.D. 301-402-1497

National Institute on Deafness and Other Communication Disorders

Tourette's Syndrome

Eligibility Requirements

Patients 18 to 80 years old with Tourette's syndrome; vocal and/or motor tics at present.

Treatment/Procedures

Neurological evaluation; PET scan; MRI scan.

Contact

Allen R. Braun, M.D. 301-402-1497

National Institute on Deafness and Other Communication Disorders

Voice Disorders

Eligibility Requirements

Persons between the ages of 18 and 80 years from families with multiple members affected with the same voice disorder.

Treatment/Procedures

Complete diagnostic testing of affected and unaffected family members is used to determine the type of disorder and the recommended treatment approach. Blood draw or buccal swab.

Contact

Christy Ludlow, Ph.D. 301-496-9365

National Institute on Deafness and Other Communication Disorders

Voice Disorders, Idiopathic (Dysphonias, Spasmodic Dysphonia)

Eligibility Requirements

Patients between 20 and 70 years with neurogenic voice disorders such as vocal fold paralysis, adductor or abductor spasmodic dysphonia and/or voice tremor.

Treatment/Procedures

Differential diagnosis using electromyography, speech and otolaryngologic examinations; evaluation for neuromuscular stimulation to control voice symptoms.

Contact

Christy Ludlow, Ph.D. 301-496-9365

National Institute on Deafness and Other Communication Disorders

Dental and Oral Disorders

Bone Augmentation, Oral Surgery

Eligibility Requirements

Patients with low jaw bone mass requiring dental implants; patients with failing dental implants.

Treatment/Procedures

Bone marrow aspiration for growth and study of bone-forming cells to develop techniques for bone augmentation in these patients.

Contact

Pamela Gehron Robey, Ph.D. 301-496-4563
National Institute of Dental Research

Edentulism, Low Jaw Bone Mass, Oral Surgery

Eligibility Requirements

Patients without teeth, or patients with low jaw bone mass requiring dental implants, patients with failing dental implants.

Treatment/Procedures

Bone marrow aspiration for growth and study of bone-forming cells to develop techniques for bone augmentation at a future date in these patients.

Contact

Pamela Gehron Robey, Ph.D. 301-496-4563
National Institute of Dental Research

Facial Pain, Chronic

Eligibility Requirements

Patients with pain related to the muscles of mastication, temporomandibular joint, or trigeminal nerve; uncomplicated by prior treatments.

Treatment/Procedures

Novel diagnostic and therapeutic modalities.

Contact

Raymond Dionne, D.D.S., Ph.D. 301-496-0294
National Institute of Dental Research

Impacted Third Molars, Oral Surgery

Eligibility Requirements

Patients in need of removal of third molars ("wisdom teeth") who reside in the greater Washington area.

Treatment/Procedures

Oral surgery is performed with intravenous sedation and local anesthesia using standard drugs and surgical procedures. Novel analgesics and analgesic mechanisms are evaluated over the first few hours up to two days following surgery.

Contact

Raymond A. Dionne, D.D.S., Ph.D. 301-496-5483
National Institute of Dental Research

Neuralgia, Post-herpetic

See *Neurological Disorders and Stroke*.

Oral Lichen Planus

Eligibility Requirements

Patients with oral lichen planus with or without involvement of other sites.

Treatment/Procedures

Diagnostic procedures; drug therapies.

Contact

Jane C. Atkinson, D.D.S. 301-402-0448
National Institute of Dental Research

Oral Medicine Disorders

Eligibility Requirements

Patients with unusual oral/dental/craniofacial disorders or oral disorders of unknown etiology.

Treatment/Procedures

Diagnostic evaluation; drug and/or surgical therapy.

Contact

Philip C. Fox, D.D.S. 301-496-4278
National Institute of Dental Research

Salivary Gland Dysfunction

Eligibility Requirements

Patients with symptoms of dry mouth and salivary gland hypofunction.

Treatment/Procedures

Evaluation and treatment of the secretory dysfunction.

Contact

Philip C. Fox, D.D.S. 301-496-4278
National Institute of Dental Research

Sjögren's Syndrome

Eligibility Requirements

Patients with diagnosed or suspected primary Sjögren's syndrome.

Treatment/Procedures

Confirmation of diagnosis; studies of salivary gland function; treatments of the underlying exocrinopathy.

Contact

Philip C. Fox, D.D.S. 301-496-4278
National Institute of Dental Research

Diabetes

Diabetes Mellitus

Eligibility Requirements

Patients with severe insulin resistance, especially in association with acanthosis nigricans and/or hyperandrogenism and/or lipodystrophy.

Treatment/Procedures

Research studies including blood tests for obtaining DNA.

Contact

Simeon Taylor, M.D. 301-496-4658

National Institute of Diabetes and Digestive and Kidney Diseases

Drug Abuse

Attention Deficit Hyperactivity Disorder

Eligibility Requirements

Adolescents with history of ADHD.

Treatment/Procedures

Neurological and neuropsychological assessments. Family history.

Contact

Recruitment Unit 410-550-1502

National Institute on Drug Abuse

Cocaine Abuse/Addiction

Eligibility Requirements

Patients 21 to 45 years old; history of cocaine abuse; HIV-negative or HIV-positive.

Treatment/Procedures

Drug and treatment studies; neuropsychiatric and neurologic evaluation; positron emission tomography (PET); magnetic resonance imaging (MRI); cardiovascular monitoring; molecular genetic and twin studies; and immunological studies.

Contact

Recruitment Unit 410-550-1502

National Institute on Drug Abuse

Heroin Abuse/Addiction

Eligibility Requirements

Patients between 21 to 45 years old with history of heroin abuse; HIV-positive and HIV-negative volunteers sought.

Treatment/Procedures

Neuropsychological, neuropsychiatric and neurologic evaluation; magnetic resonance imaging; molecular genetic and twin studies; treatment studies.

Contact

Recruitment Unit 410-550-1502

National Institute on Drug Abuse

Marijuana Abuse/Addiction

Eligibility Requirements

Volunteers between 21-45 years of age with marijuana abuse.

Treatment/Procedures

Neurological and neuropsychological assessments; magnetic resonance imaging; genetic and twin studies; EEG; cardiovascular monitoring; experimental drug trial.

Contact

Recruitment Unit 410-550-1502

National Institute on Drug Abuse

Methadone Use

Eligibility Requirements

Patients between 21-45 years old with a long history of methadone maintenance who are HIV-negative or HIV-positive.

Treatment/Procedures

Neuropsychological assessments; magnetic resonance imaging; molecular genetic studies; neurological examination.

Contact

Recruitment Unit 410-550-1502

National Institute on Drug Abuse

Methamphetamine Abuse/Addiction

Eligibility Requirements

Volunteers between ages 21-55 years with history of METH abuse.

Treatment/Procedures

Neurological and neuropsychological assessments; magnetic resonance imaging; molecular genetic and twin studies; EEG.

Contact

Recruitment Unit 410-550-1502

National Institute on Drug Abuse

Nicotine Abuse/Addiction

Eligibility Requirements

Patients between 21-45 years old with a long history of nicotine abuse.

Treatment/Procedures

Drug studies; positron emission tomography (PET); neuropsychological studies; molecular genetic and twin studies.

Contact

Recruitment Unit 410-550-1502
National Institute on Drug Abuse

Phencyclidine Abuse/Addiction

Eligibility Requirements

Volunteers between 21-45 years old with history of PCP abuse.

Treatment/Procedures

Neuropsychological and neurological evaluation; magnetic resonance imaging; molecular genetic and twin studies.

Contact

Recruitment Unit 410-550-1502
National Institute on Drug Abuse

Endocrine Disorders

Addison's Disease

Eligibility Requirements

Patients ages 18 to 50 years old; primary adrenal insufficiency in the absence of any other autoimmune disease.

Treatment/Procedures

Administration of Interleukin-6; clinical and biochemical evaluation of Addison's disease.

Contact

Dimitris A. Papanicolaou, M.D. 301-496-4686
National Institute of Child Health and Human Development

Adrenal Hyperplasia/Congenital 21-Hydroxylase or 11-Hydroxylase Deficiency

Eligibility Requirements

Bone age of 1 to 11 years (girls) or 1 to 13 years (boys).

Treatment/Procedures

Randomized clinical trial of flutamide (an antiandrogen), testolactone (an aromatase inhibitor) and reduced hydrocortisone dose vs. conventional treatment.

Contact

Deborah Merke, M.D. 301-496-4686
National Institute of Child Health and Human Development

Adrenal Insufficiency

See *Addison's Disease*.

Carney Complex/Primary Pigmented Adrenocortical Dysplasia (PPNAD)

Eligibility Requirements

Sporadic or familial cases of patients with Carney Complex and/or PPNAD.

Treatment/Procedures

DNA studies; surgical treatment (adrenalectomy if needed).

Contact

Constantine A. Stratakis, M.D. 301-496-4686
National Institute of Child Health and Human Development

Cushing's Syndrome

Eligibility Requirements

Patients age 18 to 50 years old; suspicion of Cushing's syndrome, based on increased urinary-free cortisol and clinical findings.

Treatment/Procedures

Administration of Interleukin-6; diagnostic evaluation and treatment of Cushing's syndrome.

Contact

Dimitris A. Papanicolaou, M.D. 301-496-4686
National Institute of Child Health and Human Development

Cushing's Syndrome

Eligibility Requirements

Patients 18 to 65 years old suspected of having Cushing's syndrome.

Treatment/Procedures

Surgical treatment after confirmation of diagnosis, including inferior petrosal sinus and jugular venous sampling.

Contact

Lynnette K. Nieman, M.D. 301-496-8935
National Institute of Child Health and Human Development

Cystinosis

Eligibility Requirements

Positive diagnosis of nephropathic, juvenile, or benign cystinosis (pre-transplant or post-transplant).

Treatment/Procedures

Examination of clinical characteristics; treatment with cysteamine; investigation of defective gene.

Contact

William A. Gahl, M.D., Ph.D. 301-496-9101
National Institute of Child Health and Human Development

Diabetic Neuropathy

See *Neurological Disorders and Stroke*.

Diabetic Neuropathy, Painful

See *Neurological Disorders and Stroke*.

Growth Hormone Excess

Eligibility Requirements

Patients with known or suspected acromegaly or gigantism.

Treatment/Procedures

Endocrine studies as well as medical and surgery therapy are offered.

Contact

Monica Skarulis, M.D.

Richard Eastman, M.D. 301-496-4658

National Institute of Diabetes and Digestive and Kidney Diseases

Hermansky-Pudlak Syndrome

Eligibility Requirements

Positive diagnosis.

Treatment/Procedures

Clinical characterization of disorder; investigation into basic defect; skin biopsy for cell culture.

Contact

William A. Gahl, M.D., Ph.D. 301-496-9101

National Institute of Child Health and Human Development

Hyperparathyroidism, Primary

Eligibility Requirements

Sporadic or familial hyperparathyroidism, including multiple endocrine neoplasia type 1. With or without prior neck surgery.

Treatment/Procedures

Multiple preoperative parathyroid gland imaging tests, depending upon indications. Surgical parathyroidectomy. Fresh or cryopreserved parathyroid autografts. Angiographic ablation of certain mediastinal adenomas.

Contact

Stephen Marx, M.D. 301-496-5051

Monica Skarulis, M.D. 301-496-6087

Allen Spiegel, M.D. 301-496-4128

National Institute of Diabetes and Digestive and Kidney Diseases

Hypoglycemia

Eligibility Requirements

Adult patients with documented plasma glucose of 45 mg/dl or less are sought for studies of hypoglycemia due to insulinoma, autoimmune causes or unexplained etiology.

Treatment/Procedures

Endocrine studies as well as medical and surgical therapy are offered. Research includes new tumor localization techniques.

Contact

Monica Skarulis, M.D. 301-496-4658

National Institute of Diabetes and Digestive and Kidney Diseases

Hypoparathyroidism, Parathyroid Disease

Eligibility Requirements

Patients with hypoparathyroidism ages 4 to 65 years old without significant renal or liver insufficiency.

Treatment/Procedures

Treatment with subcutaneous parathyroid hormone for 6 months, then randomized to either PTH or conventional therapy (Rocaltrol) for long-term outpatient follow-up.

Contact

Karen K. Winer, M.D.

Gordon B. Cutler Jr., M.D. 301-496-4686

National Institute of Child Health and Human Development

Lysosomal Storage Disorders of Unknown Etiology

Eligibility Requirements

Strong clinical evidence of lysosomal storage; known lysosomal disorders eliminated

Treatment/Procedures

Skin biopsy for basic research.

Contact

William A. Gahl, M.D., Ph.D. 301-496-9101

National Institute of Child Health and Human Development

Male Pseudohermaphroditism–5-alpha Reductase (Type 2) Deficiency

Eligibility Requirements

Adult males suspected of having male pseudohermaphroditism due to 5-alpha reductase deficiency based on clinical findings and a testosterone/DHT ratio greater than 16.

Treatment/Procedures

Administration of topical dihydrotestosterone cream for 6 months. Evaluation of penis and prostate size, body composition, bone density and turnover, hormonal profiles, and psychological responses.

Contact

Frank Czerwiec, M.D., Ph.D. or Michael Collins, M.D. 301-496-4686
National Institute of Child Health and Human Development

Prader-Willi Syndrome

Eligibility Requirements

Children and adolescents with Prader-Willi syndrome.

Treatment/Procedures

Evaluation of hypothalamic-pituitary-growth hormone axis function; treatment with hexarelin, a growth hormone-releasing hormone analogue.

Contact

Constantine A. Stratakis, M.D. 301-496-4686
National Institute of Child Health and Human Development

Precocious Puberty, Familial Male (FMPP)

Eligibility Requirements

Familial male precocious puberty with bone age \leq 14 years.

Treatment/Procedures

Treatment with an antiandrogen (spironolactone) and two aromatase inhibitors (testolactone and fadrozole) to compare their safety and efficacy.

Contact

Ellen Leschek, M.D. 301-496-4686
National Institute of Child Health and Human Development

Precocious Puberty, McCune Albright Syndrome

Eligibility Requirements

Girls less than 10 years of age with confirmed diagnosis of gonadotropin-independent precocious puberty.

Treatment/Procedures

Investigational drug therapy with an aromatase enzyme inhibitor.

Contact

Susan B. Nunez, M.D. 301-496-6153

National Institute of Child Health and Human Development

Pseudohypoparathyroidism

Eligibility Requirements

Hypocalcemia, pseudohypoparathyroidism, with or without Albright's hereditary osteodystrophy.

Treatment/Procedures

Evaluation of resistance to parathyroid hormone. Evaluation of genes underlying this state.

Contact

Lee Weinstein, M.D. 301-402-2923

National Institute of Diabetes and Digestive and Kidney Diseases

Rickets or Osteomalacia

Eligibility Requirements

Patients with hypophosphatemia, hypocalcemia, vitamin D resistant rickets, or calcitriol resistance.

Treatment/Procedures

Vitamin D analogs, calcium, and/or phosphate. Tumors causing oncogenic osteomalacia (tumor induced osteomalacia) may be removed.

Contact

Stephen Marx, M.D. 301-496-5051

Monica Skarulis, M.D. 301-496-6087

National Institute of Diabetes and Digestive and Kidney Diseases

Short Stature

Eligibility Requirements

Boys 10 to 15 years and girls 9 to 15 years who are extremely short for age (height of a child 2 to 3 years younger) but otherwise healthy.

Treatment/Procedures

Growth hormone or placebo.

Contact

Ellen Leschek, M.D. 301-496-4686

National Institute of Child Health and Human Development

Short Stature, Non-growth Hormone Deficient and Growth Hormone Resistant

Eligibility Requirements

Prepubertal children age 3 to 15 years with either non-growth hormone deficient extreme short stature or growth hormone insensitivity (growth hormone receptor deficiency or growth hormone gene deletion).

Treatment/Procedures

Treatment with recombinant human insulin like growth factor-I (rhIGF-I).

Contact

Ellen Leschek, M.D. 301-496-4686

National Institute of Child Health and Human Development

Short Stature and Stress

Eligibility Requirements

Children and adolescents with short stature and evidence for anxiety and stress behaviors.

Treatment/Procedures

Growth hormone-stimulation studies; evaluation of hypothalamic-pituitary-adrenal axis function; measurements of anxiety and stress behaviors.

Contact

Constantine Stratakis, M.D. 301-496-4686

National Institute of Child Health and Human Development

Thyroid Disease

Eligibility Requirements

Patients with known or suspected syndrome of inappropriate secretion of TSH due to thyrotropin secreting pituitary adenomas are sought. Patients with autoimmune thyroid disease, particularly Grave's disease, with severe extrathyroidal manifestations.

Treatment/Procedures

Endocrine and genetic studies as well as medical and surgical therapy are offered.

Contact

Monica Skarulis, M.D. 301-496-1913

National Institute of Diabetes and Digestive and Kidney Diseases

Thyroid Neoplasms

See *Cancer*.

Eye Diseases

Diabetic Retinopathy

Eligibility Requirements

Patients 18 to 69 years old with Type I or II diabetes mellitus and previously treated or untreated diabetic retinopathy.

Treatment/Procedures

In addition to ocular exam, patients assessed with annual psychophysical tests to evaluate natural history of diabetic retinopathy; laser photocoagulation given to patients requiring treatment; patients assessed clinically every 4 to 6 months with follow-up for 5 years.

Contact

Sally McCarthy, R.N., M.S.N. 301-496-3469
National Eye Institute

Dry Eye

Eligibility Requirements

Patients with dry eye syndrome sought for clinical trials of new therapies for this condition.

Treatment/Procedures

New medical therapeutic agents.
New diagnostic procedures.

Contact

Janine A. Smith, 301-435-5139
National Eye Institute

Eye Disorders, Anterior Chamber Anomalies

Eligibility Requirements

Patients with inherited ocular disorders affecting anterior chamber and lens, including Reiger's, Peter's and Axenfeld's ICE, aniridia, and congenital cataract.

Treatment/Procedures

Appropriate diagnostic studies to elucidate diagnosis will be performed and correlated with the molecular defect.

Contact

Muriel I. Kaiser-Kupfer, M.D. 301-496-3577
National Eye Institute

Eye Disorders, ICE Syndrome (essential iris atrophy, Chandler syndrome, Cogan-Reese syndrome [irido-corneal-endothelial syndromes])

Eligibility Requirements

Patients of any age or sex with ICE syndrome.

Treatment/Procedures

Appropriate diagnostic studies to elucidate diagnosis, investigate molecular defect, and plan therapy in conjunction with referring eye care professional.

Contact

Carl Kupfer, M.D. 301-496-2234
National Eye Institute

Eye Movement Disorders

Eligibility Requirements

Abnormalities of eye movements including nystagmus, fixational instability, and problems with saccades, smooth pursuit or vergence eye movements.

Treatment/Procedures

Full neuro-ophthalmic evaluation including visual field testing and eye movement recordings.

Contact

Edmond J. FitzGibbon, M.D. 301-496-7144
National Eye Institute

Macular Degeneration, Cataract, or Normal Visual Function, Age-related

Eligibility Requirements

African American males and females ages 55 to 79 years.

Treatment/Procedures

In addition to ocular exam, patients assessed with annual lens and fundus photography to evaluate natural history of cataract and age-related macular degeneration; patients randomly assigned to antioxidants (beta carotene, vitamins C and E), zinc, combination of antioxidants and zinc, or placebo to assess whether supplements retard or prevent development of these two ocular conditions; patients examined every 6 months with follow-up for 5 years.

Contact

Sally McCarthy, R.N., M.S.N. 301-496-3469
National Eye Institute

Macular Degeneration, Hereditary

Eligibility Requirements

Includes retinitis pigmentosa; juvenile macular dystrophy; Stargardt's disease; Usher syndrome; Bietti's crystalline dystrophy; Best's disease; fundus flavimaculatus; gyrate atrophy of the choroid and retina; congenital and acquired color vision deficiencies; cone dystrophy; etc.

Treatment/Procedures

To elucidate classification of disease process, electrophysiological testing performed and correlated with molecular mechanism.

Contact

Muriel I. Kaiser-Kupfer, M.D. 301-496-3577
National Eye Institute

Retinal Degeneration, Hereditary

Eligibility Requirements

Includes retinitis pigmentosa; juvenile macular dystrophy; Stargardt's disease; Usher syndrome; Bietti's crystalline dystrophy; Best's disease; fundus flavimaculatus; gyrate atrophy of the choroid and retina; congenital and acquired color vision deficiencies; cone dystrophy, etc.

Treatment/Procedures

To elucidate classification of disease process, electrophysiological testing performed and correlated with molecular mechanism.

Contact

Muriel I. Kaiser-Kupfer, M.D. 301-496-3577
National Eye Institute

Retinitis, Cytomegalovirus (CMV) Infection

Eligibility Requirements

Patients with CMV retinitis sought for clinical trials of new therapies for this ocular condition.

Treatment/Procedures

New medical therapy including the effect of combination anti-HIV therapy on CMV retinitis.

Contact

Scott M. Whitcup, M.D. 301-496-9058
National Eye Institute

Retinitis Pigmentosa

See *Macular Degeneration, Hereditary*.

Usher Syndrome

See *Macular Degeneration, Hereditary*.

Uveitis

Eligibility Requirements

Adults and children with uveitis, including disorders such as anterior uveitis, ocular sarcoidosis, ocular toxoplasmosis, pars planitis, birdshot choroidopathy, serpiginous retinochoroidopathy, Harada's disease, retinal vasculitis, intraocular lymphoma and uveitic cataracts, and juvenile rheumatoid arthritis.

Treatment/Procedures

New medical and surgical treatments including immunosuppressive agents, induction of oral tolerance, new immunotherapy and cataract surgery for patients with uveitis-induced cataract.

Contact

Scott M. Whitcup, M.D. 301-496-9058

Robert B. Nussenblatt, M.D. 301-496-3123

National Eye Institute

Gastrointestinal Diseases

Gluten-sensitive Enteropathy

Eligibility Requirements

Patients with gluten-sensitive enteropathy.

Treatment/Procedures

Studies of immunologic and genetic abnormalities.

Contact

Warren Strober, M.D. 301-496-9663

National Institute of Allergy and Infectious Diseases

Zollinger-Ellison Syndrome

Eligibility Requirements

Patients 18 years old or older with Zollinger-Ellison syndrome.

Treatment/Procedures

Confirm diagnosis. Localize tumor (ultrasound, CT scan, somatostatin receptor scintigraphy, MR imaging, selective angiography, endoscopic ultrasound). Selected patients eligible for surgery and tumoricidal therapy.

Contact

Robert T. Jensen, M.D. 301-496-4201

National Institute of Diabetes and Digestive and Kidney Diseases

Genetic and Inherited Diseases

Anomaly Syndrome/Multiple Congenital

Eligibility Requirements

Three minor anomalies, or one minor and one major anomaly; growth or mental retardation or developmental delay; normal G-banded karyotype; patient must not meet clinical criteria for any known syndrome and must have no family history of a similar disorder; both biological parents must be available for study.

Treatment/Procedures

Medical genetics evaluation; blood drawn for genetic studies.

Contact

Leslie G. Biesecker, M.D. 301-402-2041
Kathy Peters, M.S. 301-402-9653
National Human Genome Research Institute

Bacterial Infections, Recurrent

Eligibility Requirements

Patients with recurrent pyogenic infections; patients with eczema, elevated IgE, and deep-seated staphylococcal infections.

Treatment/Procedures

Study of host defense mechanisms, with emphasis on leukocyte function; improved treatment modalities.

Contact

John I. Gallin, M.D. 301-496-4114
National Institute of Allergy and Infectious Diseases

Bipolar Affective Disorder (Genetic Study)

Eligibility Requirements

Individuals with bipolar affective disorder (manic-depressive illness) having several other family members also affected with bipolar disorder or recurrent depression.

Treatment/Procedures

Studies are conducted to identify genetic factors that may influence susceptibility to bipolar affective disorder. Participation requires a blood sample and may include a diagnostic interview.

Contact

Kay Kuhns 301-496-0373
Edward I. Ginns, M.D., Ph.D. 301-496-0373
National Institute of Mental Health

Breast Cancer, Hereditary

See *Cancer*.

Chediak-Higashi Syndrome**Eligibility Requirements**

Patients with Chediak-Higashi syndrome.

Treatment/Procedures

Study of the role of lysosomal enzymes in pathogenesis and function of the phagocytic system.

Contact

John I. Gallin, M.D. 301-496-4114
National Institute of Allergy and Infectious Diseases

Chronic Granulomatous Disease of Childhood**Eligibility Requirements**

Patients with chronic granulomatous disease of childhood.

Treatment/Procedures

Studies of host defenses and assessment of genetic basis of the disease; long-term management of acute and chronic problems provided; clinical trials of therapeutic agents; pilot gene therapy trials.

Contact

John I. Gallin, M.D. 301-496-4114
Harry Malech, M.D. 301-496-1344
National Institute of Allergy and Infectious Diseases

Colorectal Cancer, Hereditary Non-Polyposis (Lynch Syndrome)

See *Cancer*.

Connective Tissue Disorders (Heritable)

See *Arthritis (Musculoskeletal and Skin Diseases)*.

Cystinosis

Eligibility Requirements

Positive diagnosis of nephropathic, juvenile, or benign cystinosis (pre-transplant or post-transplant).

Treatment/Procedures

Examination of clinical characteristics; treatment with cysteamine; investigation of defective gene.

Contact

William A. Gahl, M.D., Ph.D. 301-496-9101
National Institute of Child Health and Human Development

Down Syndrome

Eligibility Requirements

Adults over 18 years old with Down syndrome; mild to moderate mental retardation; with or without dementia.

Treatment/Procedures

Neuropsychology; structural MRI; MR spectroscopy; PET scanning with cognitive stimulation; cerebrospinal fluid examination.

Contact

Mark Schapiro, M.D. 301-594-7764
National Institute on Aging

Familial Mediterranean Fever

Eligibility Requirements

Adult and pediatric patients with suspected familial Mediterranean fever (FMF) as well as family members of patients with known FMF.

Treatment/Procedures

Genetic testing; genetic counseling available.

Contact

Daniel L. Kastner, M.D., Ph.D. 301-496-8364
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Fragile X Disorder

Eligibility Requirements

Females over the age of 18 who have fragile X disorder.

Treatment/Procedures

Positron emission tomography scans.

Contact

Alan Zametkin, M.D. 301-496-4707

National Institute of Mental Health

Fragile X Syndrome

Eligibility Requirements

Adults over 18 years old with fragile X syndrome.

Treatment/Procedures

Neuropsychology; structural MRI; MR spectroscopy; PET scanning with cognitive stimulation.

Contact

Lori Beason-Held 301-594-7760

National Institute on Aging

Gaucher Disease/Lysosomal Storage Disorders

Eligibility Requirements

Individuals with type 1, 2, or 3 Gaucher disease. Individuals with other lysosomal storage disorders (such as Fabry disease).

Treatment/Procedures

Comprehensive evaluation of clinical status and laboratory manifestations in patients with Gaucher disease. Individuals with other lysosomal disorders such as Fabry disease are also studied. Selected patients may qualify for participation in treatment protocols.

Contact

Kay Kuhns 301-496-0373

Ellen Sidransky, M.D. 301-496-0373

National Institute of Mental Health

Gene Therapy for Severe Combined Immunodeficiency (SCID) due to Adenosine Deaminase (ADA) Deficiency

Eligibility Requirements

Patients with adenosine deaminase deficiency SCID.

Treatment/Procedures

Patients are treated with autologous lymphocytes or hematopoietic stem cells that have been genetically corrected ex vivo by the insertion of a normal copy of the ADA gene using a modified retroviral vector. Repeated treatments may be administered depending on the level of gene correction and immune reconstitution achieved as determined by periodic monitoring.

Contact

R. Michael Blaese, M.D. 301-496-5396

Fabio Candotti, M.D. 301-402-1833

National Human Genome Research Institute

Genetic and Inherited Diseases

Eligibility Requirements

Patients and their families with known or suspected genetic disorders will be recruited primarily from genetic centers and subspecialty clinics across the nation. Referrals will be accepted from geneticists, genetic counselors and other health care providers and family members that express interest in participating.

Treatment/Procedures

Individuals and their families affected by disorders with a potentially genetic basis will be evaluated over time to characterize the natural and clinical history. Medical and laboratory evaluations will be completed to identify areas of management concern that have not been previously described. In addition, correlations will be established to further understanding of specific molecular alterations on phenotypic expression.

Contact

Kathy Peters, M.S. 301-402-9653

National Human Genome Research Institute

Genetic Metabolic Muscle Disease

See *Arthritis (Musculoskeletal and Skin Diseases)*.

Genodermatoses

See *Arthritis (Musculoskeletal and Skin Diseases)*.

Heritable Disorders of the Immune System (Severe Combined Immunodeficiency [SCID]), Hyper-IgE Recurrent Infection Syndrome (Job Syndrome), Autoimmune Lymphoproliferative Syndrome (ALPS)

Eligibility Requirements

Individuals and relatives of individuals with established diagnoses of disorders of the immune system, particularly X-linked SCID, hyper IgE recurrent infection syndrome (Job syndrome), or familial autoimmune disease. Large kindreds with multiple affected individuals are particularly sought. Prenatal diagnosis of certain immune disorders such as X-linked SCID are accepted. Eligibility will be determined on review of physicians' records and a family pedigree.

Treatment/Procedures

Donation of sample (blood, preserved tissue, prenatal sample or other) for genetic studies, mutation detection, and evaluation of white blood cell function.

Contact

Joie Davis, R.N. 301-435-2910
 Jennifer Puck, M.D. 301-402-2194
 National Human Genome Research Institute

Hermansky-Pudlak Syndrome

Eligibility Requirements

Positive diagnosis.

Treatment/Procedures

Clinical characterization of disorder; investigation into basic defect; skin biopsy for cell culture.

Contact

William A. Gahl, M.D., Ph.D. 301-496-9101
 National Institute of Child Health and Human Development

Hyperimmunoglobulin E Recurrent Infection (Job) Syndrome

Eligibility Requirements

Patients with extreme elevation of IgE and recurrent cutaneous and deep-seated infections with *Staphylococcus aureus*.

Treatment/Procedures

Studies of ability to mount an inflammatory response; monitoring of phagocytic cell, cytokine, and immune parameters; therapeutic interventions offered.

Contact

John I. Gallin, M.D. 301-496-4114
National Institute of Allergy and Infectious Diseases

Hypoparathyroidism, Parathyroid Disease

Eligibility Requirements

Patients with hypoparathyroidism ages 4 to 65 years old without significant renal or liver insufficiency.

Treatment/Procedures

Treatment with subcutaneous parathyroid hormone for 6 months, then randomized to either PTH or conventional therapy (Rocaltrol) for long-term outpatient follow-up.

Contact

Karen K. Winer, M.D.
Gordon B. Cutler Jr., M.D. 301-496-4686
National Institute of Child Health and Human Development

Immunodeficiency Disorders (Primary or Genetic Immunodeficiency Diseases, Particularly Severe Combined Immunodeficiency, Adenosine Deaminase Deficiency, X-linked Agammaglobulinemia, Hyper-IgM Syndrome, and Wiskott-Aldrich Syndrome)

Eligibility Requirements

Patients with primary or inherited immunodeficiency diseases.

Treatment/Procedures

Patients and possibly family members will be evaluated for the functional status of their immune system and for the genetic and molecular basis of their immunodeficiency disorder in this ongoing study of the natural history of disorders of human immunity. Upon establishment or confirmation of the specific diagnosis, a treatment plan appropriate for each patient will be presented for consideration by the patient, family, and referring physician.

Contact

R. Michael Blaese, M.D. 301-496-5396
Fabio Candotti, M.D. 301-402-1833
National Human Genome Research Institute

Immunodeficiency Disorders (X-linked [Bruton's] agammaglobulinemia, common variable hypogammaglobulinemia, IgA deficiency, hyper-IgM syndrome)

Eligibility Requirements

Patients with various immunodeficiency disorders.

Treatment/Procedures

Studies of immunologic mechanisms and appropriate therapy.

Contact

Warren Strober, M.D. 301-496-9663

National Institute of Allergy and Infectious Diseases

Lysosomal Storage Disorders of Unknown Etiology

Eligibility Requirements

Strong clinical evidence of lysosomal storage; known lysosomal disorders eliminated.

Treatment/Procedures

Skin biopsy for basic research.

Contact

William A. Gahl, M.D., Ph.D. 301-496-9101

National Institute of Child Health and Human Development

Male Pseudohermaphroditism-5-alpha Reductase (Type 2) Deficiency

Eligibility Requirements

Adult males suspected of having male pseudohermaphroditism due to 5-alpha reductase deficiency based on clinical findings and a testosterone/DHT ratio greater than 16.

Treatment/Procedures

Administration of topical dihydrotestosterone cream for 6 months. Evaluation of penis and prostate size, body composition, bone density and turnover, hormonal profiles, and psychological responses.

Contact

Frank Czerwiec, M.D., Ph.D. or Michael Collins, M.D. 301-496-4686

National Institute of Child Health and Human Development

Marfan Syndrome

Eligibility Requirements

Adult individuals of either gender affected with Marfan syndrome, previously diagnosed by a geneticist.

Treatment/Procedures

Completion of one-time survey, assessing psychological and social aspects of Marfan syndrome, particularly as they relate to living at risk for an aortic dissection. Physical examination and DNA studies are **not** part of this protocol (see *Connective Tissue Disorders*).

Contact

Kathy Peters, M.S. 301-402-9653
Barbara Biesecker, M.S. 301-496-3979
National Human Genome Research Institute

Melatonin Synthesis Dysfunction

Eligibility Requirements

Individuals with very high or very low melatonin production; individuals with phase advance and phase delay sleep syndromes.

Treatment/Procedures

Evaluation of melatonin synthesis-related genes.

Contact

David C. Klein, Ph.D. 301-496-6915
National Institute of Child Health and Human Development

Oculocerebrorenal (Lowe) Syndrome

Eligibility Requirements

Patients with clinical triad of congenital cataracts, renal tubular acidosis and developmental delay, especially when there is a family history of the condition inherited in an X-linked manner.

Treatment/Procedures

Analysis of the OCRL gene for mutations.

Contact

Robert L. Nussbaum, M.D. 301-402-2039
National Human Genome Research Institute

Osteogenesis Imperfecta

See *Arthritis (Musculoskeletal and Skin Diseases)*.

Ovarian Cancer (Hereditary)

See *Cancer*.

Pallister-Hall Syndrome**Eligibility Requirements**

Patients should have two of the following criteria: 1) polydactyly, 2) hypothalamic or structurally-related lesion, 3) imperforate anus, or 4) first degree relative with Pallister-Hall syndrome; patients with hypothalamic tumor alone also considered; blood requested from unaffected relatives that could be informative for linkage studies; patients must weigh 13 kg or more to be eligible for endocrine study. Patients with the related disorders of Oral-Facial-Digital syndrome, McKusick-Kaufman syndrome, Short Rib Polydactyly are also eligible. Please contact investigator for criteria.

Treatment/Procedures

Medical genetics examination; blood drawn for genetic evaluation; imaging studies (may include CT, MRI or ultrasound); inpatient endocrinologic evaluation.

Contact

Leslie J. Biesecker, M.D. 301-402-2041

Kathy Peters, M.S. 301-402-9653

National Human Genome Research Institute

Precocious Puberty, Familial Male (FMPP)**Eligibility Requirements**

Familial male precocious puberty with bone age \leq 14 years.

Treatment/Procedures

Treatment with an antiandrogen (spironolactone) and two aromatase inhibitors (testolactone and fadrozole) to compare their safety and efficacy.

Contact

Ellen Leschek, M.D. 301-496-4686

National Institute of Child Health and Human Development

Proteus Syndrome

Eligibility Requirements

Patients must have clinical diagnosis of Proteus syndrome or Klippel-Trenaunay-Weber syndrome made by clinical geneticist; both biological parents must be willing to donate blood samples.

Treatment/Procedures

Full medical genetics examination; peripheral blood chromosome analysis; imaging studies (may include plain films, CT, MRI, or ultrasound); biopsy of affected and unaffected tissue; photographic documentation.

Contact

Leslie J. Biesecker, M.D. 301-402-2041
Kathy Peters, M.S. 301-402-9653
National Human Genome Research Institute

Wiskott-Aldrich Syndrome (Immunodeficiency with Thrombocytopenia)

Eligibility Requirements

Patients with confirmed or suspected Wiskott-Aldrich Syndrome.

Treatment/Procedures

Patients and possibly family members will be evaluated for the function of their immune systems and platelets and for the genetic and molecular basis of their disorder in this ongoing study of the natural history of the Wiskott-Aldrich Syndrome. Upon establishment or confirmation of the diagnosis, a treatment plan appropriate for each patient will be presented for consideration by the patient, family, and referring physician.

Contact

R. Michael Blaese, M.D. 301-496-5396
Fabio Candotti, M.D. 301-402-1833
National Human Genome Research Institute

Gynecologic Disorders

Endometriosis, Severe

Eligibility Requirements

Women with invasive endometriosis requiring major surgery.

Treatment/Procedures

Surgery.

Contact

Lawrence M. Nelson, M.D. 301-496-4686

National Institute of Child Health and Human Development

Herpes Simplex Virus Infection (HSV)

See *Infectious Diseases*.

Infertility Due to Anovulation

Eligibility Requirements

Women who are 18 to 40 years old and have infertility because they fail to ovulate, and the problem is resistant to treatment with clomiphene citrate.

Treatment/Procedures

Baseline endocrine evaluation; treatment to evaluate methods of restoring ovulation.

Contact

Lawrence M. Nelson, M.D. 301-496-4686

National Institute of Child Health and Human Development

Ovarian Failure, Premature

Eligibility Requirements

Women with ovarian failure who are 18 to 40 years of age and desire fertility.

Treatment/Procedures

Baseline endocrine evaluation; treatments to evaluate methods of restoring ovulation.

Contact

Lawrence M. Nelson, M.D. 301-496-4686

National Institute of Child Health and Human Development

Ovary Syndrome, Polycystic

Eligibility Requirements

Women with polycystic ovary syndrome interested in fertility but unable to ovulate on clomiphene citrate treatment.

Treatment/Procedures

Baseline endocrine evaluation and treatments to evaluate methods of inducing ovulation.

Contact

Lawrence M. Nelson, M.D. 301-496-4686

National Institute of Child Health and Human Development

Hematologic Disorders

Aplastic Anemia

Eligibility Requirements

Patients with new onset severe disease.

Treatment/Procedures

Intensive immunosuppression, consisting of either a) antithymocyte globulin plus cyclosporine or b) cyclophosphamide plus cyclosporine.

Contact

Olga Nunez, R.N. 301-496-4462
National Heart, Lung, and Blood Institute

Aplastic Anemia

Eligibility Requirements

Patients with refractory aplastic anemia

Treatment/Procedures

Immunosuppression with 2-chlorodeoxyadenosine or growth factor therapy using stem cell factor plus granulocyte colony stimulating factor.

Contact

Olga Nunez, R.N. 301-496-4462
Mary Caples, R.N. 301-402-0797
National Heart, Lung, and Blood Institute

Beta-Thalassemia

Eligibility Requirements

Patients 18 years or older with beta-thalassemia who require transfusions infrequently (i.e., less than four times/year).

Treatment/Procedures

Treatment with drugs such as hydroxyurea aimed at correcting anemia and reducing red blood cell transfusions.

Contact

Beth Link, R.N. 301-402-3087
National Heart, Lung, and Blood Institute

Bone Marrow Transplantation

Eligibility Requirements

Patients ages 10 to 55 years old; hematologic malignancies at all stages (CML, AML, ALL, MDS, Multiple Myeloma). HLA matched sibling required.

Treatment/Procedures

Evaluate the effect of T cell depletion followed by T cell add back to prevent acute graft-versus-host disease. High risk or standard risk leukemia. Myeloma protocol includes idiotype vaccination of the donor. Autologous transplantation also available for Multiple Myeloma.

Contact

Sheila Phang, R.N. 301-402-3595
National Heart, Lung, and Blood Institute

Bone Marrow Transplantation, HLA Matched for Malignant Melanoma and Renal Cell Carcinoma

Eligibility Requirements

Patients ages 18 to 60 years old; metastatic/relapsed melanoma failing standard treatment. HLA matched sibling required.

Treatment/Procedures

Evaluate ways to prevent graft-versus-host disease and enhance graft-versus-leukemia effects.

Contact

Sheila Phang, R.N. 301-402-3595
National Heart, Lung, and Blood Institute

Bone Marrow Transplantation, HLA Matched for Older Adults

Eligibility Requirements

Patients ages 55 to 75 years old; CML, ALL, AML, MDS, CLL, HLA matched sibling required.

Treatment/Procedures

Non-myeloablative regimen to evaluate graft-versus-leukemia effect and reduce graft-versus-host disease.

Contact

Shiela Phang, R.N. 301-401-3595
National Heart, Lung, and Blood Institute

Sickle Cell Anemia and Related Syndromes (s- β thalassemia, hemoglobin SC or SD disease)**Eligibility Requirements**

Patients 18 years or older with recurrent painful crisis, leg ulcers, chronic hip pain, or other complications.

Treatment/Procedures

Treatment with drugs such as hydroxyurea, erythropoietin, 5-azacytidine and others, aimed at elevating fetal hemoglobin levels.

Contact

Griffin P. Rodgers, M.D. 301-496-0299

Beth Link, R.N. 301-402-3087

National Institute of Diabetes and Digestive and Kidney Disorders

Immunologic Diseases

Autoimmune Lymphoproliferative Syndrome (ALPS)

Eligibility Requirements

Patients 1 to 65 years of age with chronic non-malignant diffuse lymphadenopathy, splenomegaly in the absence of infections associated with these features, and increased TCR α/β CD4-CD8⁻ T cells in the peripheral blood and/or tissues.

Treatment/Procedures

A prospective study of cellular, molecular and genetic mechanisms leading to the polyclonal expansion of TCR α/β CD4-CD8⁻ T cells and associated lymphoproliferative and autoimmune disease. Objectives include advancing knowledge regarding the mechanisms of autoimmunity, normal thymic and extrathymic T cell differentiation and TCR repertoire selection. Study participants include patients and relatives of patients. Autoimmune complications of the disorder will be treated using established approaches and medications.

Contact

Stephen E. Straus, M.D. 301-496-5221
Michael C. Sneller, M.D. 301-496-0491
Jennifer M. Puck, M.D. 301-402-2194
Janet K. Dale, R.N., M.P.H. 301-496-1699
National Institute of Allergy and Infectious Diseases
National Human Genome Research Institute

Epstein-Barr Virus (EBV) Associated Chronic Immune and Lymphoproliferative Disorders

Eligibility Requirements

Patients must be at least 2 years old and have an illness of at least 3 months' duration without signs of improvement; their illness and blood test results must be compatible with an active EBV infection. Individuals who have chronic fatigue syndrome, cancer, or HIV infection are ineligible.

Treatment/Procedures

A prospective study of the spectrum of chronic immunologic and lymphoproliferative disorders related to EBV infection. Objectives include ascertainment of virus burden, evaluation of immune phenotype and competence, and studies of disease progression and management of complications.

Contact

Stephen E. Straus, M.D. 301-496-5221
Jeffery I. Cohen, M.D. 301-496-5221
Janet K. Dale, R.N. 301-496-1699
National Institute of Allergy and Infectious Diseases

Mastocytosis

Eligibility Requirements

Patients with mastocytosis and urticaria pigmentosa.

Treatment/Procedures

Study of factors responsible for symptoms and response to anti-histamine and anti-mast cell drugs.

Contact

Dean Metcalfe, M.D. 301-496-2165

National Institute of Allergy and Infectious Diseases

Urticaria Pigmentosa

Eligibility Requirements

Patients with urticaria pigmentosa and mastocytosis.

Treatment/Procedures

Study of factors responsible for symptoms and response to anti-histamine and anti-mast cell drugs.

Contact

Dean Metcalfe, M.D. 301-496-2165

National Institute of Allergy and Infectious Diseases

Vasculitis

Eligibility Requirements

Patients with systemic vasculitis, polyarteritis nodosa, Wegener's granulomatosis, and other inflammatory vascular diseases.

Treatment/Procedures

Study of immunologic parameters before, during, and after treatment with corticosteroids or cytotoxic agents.

Contact

Michael Sneller, M.D.

Carol Langford, M.D. 301-496-1124

National Institute of Allergy and Infectious Diseases

Infectious Diseases

Cryptococcosis

Eligibility Requirements

Patients with cryptococcosis.

Treatment/Procedures

Evaluation and longitudinal study.

Contact

John Bennett, M.D. 301-496-3461

National Institute of Allergy and Infectious Diseases

Epstein-Barr Virus (EBV) Associated Chronic Immune and Lymphoproliferative Disorders

See *Immunologic Diseases*.

Herpes Simplex Virus Infection (HSV)

Eligibility Requirements

Couples ages 18 or older in general good health and in a monogamous heterosexual relationship with each other. The partner with genital herpes must have evidence of prior herpes simplex type 2 (HSV-2) infection by detection of antibodies to HSV-2 in the blood, be experiencing less than 10 recurrences per year, and be off suppressive therapy upon study entry. Susceptible partners must not have a history of genital herpes or evidence of HSV-2 antibodies in their blood.

Treatment/Procedures

A randomized, multicenter, placebo-controlled Phase III trial is being conducted to determine whether valacyclovir (an oral antiviral drug) prevents the transmission of genital herpes in heterosexual couples for whom one partner has evidence of HSV-2 infection and the other does not. The partner with genital herpes will be randomized to receive 8 months of treatment (valacyclovir or placebo). The susceptible partner without evidence of HSV-2 infection will be monitored for clinical and subclinical signs of HSV-2 acquisition during study participation.

Contact

Patricia T. Hohman, R.N. 301-496-1836

Adriana R. Marques, M.D. 301-496-9054

National Institute of Allergy and Infectious Diseases

Herpes Simplex Virus Infections

Eligibility Requirements

Patients with recurrent, chronic, or severe herpes simplex virus infections.

Treatment/Procedures

Studies of viral pathogenesis, resistance to acyclovir, efficacy of new antiviral drugs, and studies of candidate vaccines.

Contact

Patricia Hohman, R.N. 301-496-9054 x610

Stephen Straus, M.D. 301-496-5221

National Institute of Allergy and Infectious Diseases

HIV Infection

Eligibility Requirements

Patients at all stages of HIV infection.

Treatment/Procedures

Clinical trials utilizing new immune-based therapies, pilot gene therapies, or antiretroviral or anti-infective therapies either alone or in combination.

Contact

Candace Kurtz 1-800-243-7644

AIDS Protocol Office

National Institute of Allergy and Infectious Diseases

HIV Infection

Eligibility Requirements

Long-term non-progressors.

Treatment/Procedures

Studies of viral burden in peripheral blood and lymphoid tissue such as lymph nodes and bone marrow.

Contact

Barbara Baird, R.N. 301-402-0980 x420 for long-term non-progressors.

Linda Ehler, R.N. 301-496-1471 for others.

National Institute of Allergy and Infectious Diseases

HIV Infection

Eligibility Requirements

Individuals experiencing acute primary infection.

Treatment/Procedures

Studies of viral burden and lymphoid tissue such as lymph nodes and bone marrow.

Contact

Oren Cohen, M.D. 301-496-5508

National Institute of Allergy and Infectious Diseases

HIV Infection

Eligibility Requirements

Oropharyngeal candidiasis unresponsive to fluconazole.

Treatment/Procedures

Study of a new formulation of itraconazole.

Contact

John Bennett, M.D. 301-496-3461

National Institute of Allergy and Infectious Diseases

HIV Infection

Eligibility Requirements

Individuals with symptomatic HIV infection or AIDS and 500 CD4 cells/mm³ or less.

Treatment/Procedures

A new nucleoside analogue, beta-fluoro-ddA, alone and in combination with other anti-HIV drugs.

Contact

Robert Yarchoan, M.D.

Jill Lietzau, R.N. 301-496-8959

National Cancer Institute

HIV Infection

Eligibility Requirements

Individuals with HIV infection and over 500 CD4 cells/mm³ who are not receiving antiretroviral therapy.

Treatment/Procedures

Vaccination with one or two HIV peptide vaccines.

Contact

Robert Yarchoan, M.D.
Jill Lietzau, R.N. 301-496-8959
National Cancer Institute

HIV Infection, Childhood

Eligibility Requirements

Children 3 months to 18 years of age with either previously untreated HIV infection or with disease that has become intolerant or refractory to treatment.

Treatment/Procedures

Antiretroviral agents (e.g., reverse transcriptase inhibitors; protease inhibitors) alone or in combination; agents to improve host immunity (e.g., IL-2, interferon gamma, HIV vaccine).

Contact

Susan Sandelli, R.N. 301-402-1391
National Cancer Institute

HIV Infection, Symptomatic or AIDS

Eligibility Requirements

Children 3 months to 18 years of age with either previously untreated HIV infection or with disease that has become intolerant or refractory to treatment.

Treatment/Procedures

Antiretroviral agents (e.g., reverse transcriptase inhibitors; protease inhibitors) alone or in combination; agents to improve host immunity (e.g., IL-2, interferon gamma, HIV vaccine).

Contact

Susan Sandelli, R.N. 301-402-1391
National Cancer Institute

Lyme Disease, Chronic

Eligibility Requirements

Individuals who are 13 to 65 years old with documented positive serology for Lyme disease (ELISA or IFA tests), confirmed by Western Blot; have had persistent symptoms and/or signs of neurologic dysfunction for at least three months; and are willing to refrain from antibiotic therapy for at least one month prior to their initial evaluation. Recruitment also includes persons diagnosed with either Lyme arthritis, Lyme disease that subsequently resolved after antibiotic treatment, or who are seropositive for Lyme infection but have never had symptoms.

Treatment/Procedures

Individuals who fulfill the study criteria will be offered antibiotic therapy upon completion of an initial evaluation that includes extensive routine and specialized assessments, inclusive of repeat blood tests for Lyme disease, neuropsychological tests, brain scan, lumbar puncture, immunologic assessment, and audiologic examination.

Contact

Adriana Marques, M.D. 1-800-772-5464 x655
Brenda Cuccherini, Ph.D., N.P. 1-800-772-5464 x608
National Institute of Allergy and Infectious Diseases

Mycobacterial Infection

Eligibility Requirements

Patients with disseminated, refractory, or multiple-drug resistant mycobacterial infections.

Treatment/Procedures

Treatment with interleukin-2.

Contact

Michael Sneller, M.D. 301-496-1124
National Institute of Allergy and Infectious Diseases

Mycobacterial Infection

Eligibility Requirements

Patients with disseminated, refractory, or multiple-drug resistant mycobacterial infections.

Treatment/Procedures

Evaluation of underlying host defense defects and treatment with interferon gamma.

Contact

Steven M. Holland, M.D. 301-402-7684

National Institute of Allergy and Infectious Diseases

Varicella-Zoster Infection

Eligibility Requirements

Patients with varicella-zoster infection.

Treatment/Procedures

Study of viral pathogenesis, resistance to acyclovir.

Contact

Stephen Straus, M.D. 301-496-5221

National Institute of Allergy and Infectious Diseases

Infectious Diseases and Parasitic Diseases

Parasitic Diseases (amebiasis, Chagas' disease, cryptosporidiosis, cysticercosis, echinococcosis, filariasis, giardiasis, leishmaniasis, loiasis, malaria, onchocerciasis, schistosomiasis, strongyloidiasis, toxoplasmosis)

Eligibility Requirements

Patients with parasitic infections.

Treatment/Procedures

Specialized tests, procedures, and medications available to diagnose, characterize, and treat parasitic infections.

Contact

Franklin Neva, M.D. 301-496-2486

Theodore Nash, M.D. 301-496-6920

Thomas Nutman, M.D. 301-496-5398

National Institute of Allergy and Infectious Diseases

Kidney Disorders

Lupus Nephritis, Membranous Nephropathy

Eligibility Requirements

Patients with idiopathic or lupus membranous nephropathy and at least 2 gm per day proteinuria.

Treatment/Procedures

Evaluation includes immunologic studies, renal function tests and analysis of renal pathology. Therapeutic studies involve corticosteroids, cyclophosphamide, cyclosporin A and fludarabine.

Contact

Howard A. Austin III, M.D. 301-496-3092

James E. Balow, M.D. 301-496-4181

Dimitros T. Boumpas, M.D. 301-496-4094

National Institute of Diabetes and Digestive and Kidney Diseases

Focal Segmental Glomerulosclerosis

Eligibility Requirements

Patients with idiopathic FSGS, HIV-associated FSGS, heroin-associated FSGS, and collapsing glomerulopathy, excluding those patients with FSGS secondary to reduced nephron mass, interstitial nephritis, and reflux nephropathy, or associated with other forms of glomerular disease.

Treatment/Procedures

Evaluation includes renal function tests and analysis of renal pathology. Research studies include genetic testing to identify an FSGS risk locus and therapeutic studies of steroid-resistant FSGS.

Contact

Jeffrey Kopp, M.D. 301-594-3403

Howard A. Austin III, M.D. 301-435-5055

National Institute of Diabetes and Digestive and Kidney Diseases

Liver Diseases

Cirrhosis, Primary Biliary

Eligibility Requirements

Adult patients over 18 years old with primary biliary cirrhosis.

Treatment/Procedures

Patients will undergo medical evaluation and immunological assessment. Patients will be advised on routine therapies.

Contact

Jay H. Hoofnagle, M.D. 301-496-1333

Jake Liang, M.D. 301-496-1721

National Institute of Diabetes and Digestive and Kidney Diseases

Hepatitis B, Chronic

Eligibility Requirements

Adult patients over 18 years old with chronic hepatitis B as shown by elevations in aminotransferases and presence of HBsAg and HBV DNA in serum.

Treatment/Procedures

After medical evaluation and liver biopsy, patients will be eligible to receive a course of lamivudine, an oral antiviral agent. Patients with atypical forms of hepatitis (absence of HBeAg or presence of glomerulonephritis) are also eligible to receive lamivudine. Patients will be followed regularly during and after treatment and undergo a second liver biopsy one year after starting treatment.

Contact

Adriana Marques, M.D. 301-496-9054 ext. 665 1-800-772-5464 ext. 665

Daryl Lau, M.D. 301-402-7147

Jay H. Hoofnagle, M.D. 301-496-1333

National Institute of Allergy and Infectious Diseases

National Institute of Diabetes and Digestive and Kidney Diseases

Hepatitis C, Chronic

Eligibility Requirements

Adult patients over 18 years old with chronic hepatitis C as shown by elevations in aminotransferases and presence of anti-HCV in serum who have not previously received alpha interferon or did not respond to alpha interferon in the past.

Treatment/Procedures

After medical evaluation and liver biopsy, patients who have not received treatment previously will receive alpha interferon for one year. The dose of interferon will be escalated if there is no response in the first 3 months of treatment. Previous nonresponders to interferon will receive a combination of alpha interferon and ribavirin, an oral antiviral agent. Patients will be followed closely during and after treatment and undergo a second liver biopsy 6 months after stopping therapy.

Contact

Daryl Lau, M.D. 301-402-7147

Jay H. Hoofnagle, M.D. 301-496-1333

National Institute of Diabetes and Digestive and Kidney Diseases

Hepatitis D, Chronic

Eligibility Requirements

Adult patients over 18 years old with chronic hepatitis D (delta hepatitis) as shown by elevations in aminotransferases and presence of HBeAg, HBsAg and anti-HDV in serum.

Treatment/Procedures

After medical evaluation and liver biopsy, patients will be eligible to receive a 12-month course of lamivudine, an oral antiviral agent. Patients will be followed regularly during and after treatment and undergo a second liver biopsy one year after starting treatment.

Contact

Daryl Lau, M.D. 301-402-7147

Jay H. Hoofnagle, M.D. 301-496-1333

National Institute of Diabetes and Digestive and Kidney Diseases

Metabolic Disorders

Cystinosis

Eligibility Requirements

Positive diagnosis of nephropathic, juvenile, or benign cystinosis (pre-transplant or post-transplant).

Treatment/Procedures

Examination of clinical characteristics; treatment with cysteamine; investigation of defective gene.

Contact

William A. Gahl, M.D., Ph.D. 301-496-9101
National Institute of Child Health and Human Development

Hermansky-Pudlak Syndrome

Eligibility Requirements

Positive diagnosis.

Treatment/Procedures

Clinical characterization of disorder; investigation into basic defect; skin biopsy for cell culture.

Contact

William A. Gahl, M.D., Ph.D. 301-496-9101
National Institute of Child Health and Human Development

Lysosomal Storage Disorders of Unknown Etiology

Eligibility Requirements

Strong clinical evidence of lysosomal storage; known lysosomal disorders eliminated.

Treatment/Procedures

Skin biopsy for basic research.

Contact

William A. Gahl, M.D., Ph.D. 301-496-9101
National Institute of Child Health and Human Development

Neurological Disorders and Stroke

Acalculia

Eligibility Requirements

Patients ages 18 to 80 years old; no other major concurrent disease; capable of participating in cognitive studies; primary problem in calculation and/or number recognition.

Treatment/Procedures

Cognitive studies; mood state and personality evaluation; magnetic resonance imaging scan of the brain; neuropsychological evaluation; functional neuroimaging; neurological evaluation; neurophthalmological examination.

Contact

Jordan Grafman, Ph.D. 301-496-0220
National Institute of Neurological Disorders and Stroke

Agnosia/Prosopagnosia

Eligibility Requirements

Patients ages 18 to 80 years old; no other major concurrent disease; capable of participating in cognitive studies; agnosia is the primary deficit.

Treatment/Procedures

Cognitive studies; mood state and personality evaluation; magnetic resonance imaging scan of the brain; neuropsychological evaluation; functional neuroimaging; neurological evaluation; and neurophthalmological examination.

Contact

Jordan Grafman, Ph.D. 301-496-0220
National Institute of Neurological Disorders and Stroke

Alzheimer's Disease

Eligibility Requirements

Patients with a diagnosis of possible or probable Alzheimer's disease including preclinical, mild, or moderately advanced stages.

Treatment/Procedures

Drug therapy aimed at treating symptoms and slowing disease progression; biochemical studies aimed at eliciting pathogenesis as well as preventive and treatment modalities.

Contact

Marjorie Gillespie, R.N. 301-496-4604
National Institute of Neurological Disorders and Stroke

Amnesia

Eligibility Requirements

Patients ages 18 to 80 years old; no other major concurrent disease; capable of participating in cognitive studies; amnesia is the sole or primary deficit.

Treatment/Procedures

Cognitive studies; mood state and personality evaluation; magnetic resonance imaging scan of the brain; neuropsychological evaluation; functional neuroimaging; neurological evaluation; neurophthalmological examination.

Contact

Jordan Grafman, Ph.D. 301-496-0220
National Institute of Neurological Disorders and Stroke

Amputees

Eligibility Requirements

Single limb amputations, either upper or lower limb, in persons in otherwise good health.

Treatment/Procedures

Physiological studies including EEG and transcranial magnetic stimulation; neuroimaging studies including PET and functional MRI. Patients with phantom pain may enroll in treatment protocols.

Contact

Leonardo Cohen, M.D. via Quentis Scott 301-496-0600
National Institute of Neurological Disorders and Stroke

Anomia/Naming Impairment

Eligibility Requirements

Patients ages 18 to 80 years old; no other major concurrent disease; capable of participating in cognitive studies; sole or primary problem in naming pictures or remembering names of objects or animals.

Treatment/Procedures

Cognitive studies; mood state and personality evaluation; magnetic resonance imaging scan of the brain; neuropsychological evaluation; functional neuroimaging; neurological evaluation; neurophthalmological examination.

Contact

Jordan Grafman, Ph.D. 301-496-0220
National Institute of Neurological Disorders and Stroke

Anoxia

Eligibility Requirements

Patients ages 18 to 80 years old; no other major concurrent disease; capable of participating in cognitive studies.

Treatment/Procedures

Cognitive studies; mood state and personality evaluation; magnetic resonance imaging scan of the brain; neuropsychological evaluation; functional neuroimaging; neurological evaluation; neurophthalmological examination.

Contact

Jordan Grafman, Ph.D. 301-496-0220
National Institute of Neurological Disorders and Stroke

Brain Tumor

See *Cancer*.

Carbon Monoxide Poisoning

Eligibility Requirements

Patients ages 18 to 80 years old; no other major concurrent disease; capable of participating in cognitive studies.

Treatment/Procedures

Cognitive studies; mood state and personality evaluation; magnetic resonance imaging scan of the brain; neuropsychological evaluation; functional neuroimaging; neurological evaluation; neurophthalmological examination.

Contact

Jordan Grafman, Ph.D. 301-496-0220
National Institute of Neurological Disorders and Stroke

Cerebellar Disorders

Eligibility Requirements

Cerebellar ataxia affecting control of the upper extremities or upright balance without weakness or sensory loss.

Treatment/Procedures

Physiological studies of the motor control problem and advice on appropriate therapy; opportunities periodically available for participation in protocols with new, experimental medications.

Contact

Mark Hallett, M.D. via Quentis Scott 301-496-0600
National Institute of Neurological Disorders and Stroke

Cerebrovascular Disease

Eligibility Requirements

Patients with known or suspected cerebrovascular disease who are eligible for care in Department of Defense hospitals (National Naval Medical Center).

Treatment/Procedures

Drug therapy; carotid endarterectomy; neuroimaging; examination of cytokines, leukocytes and other inflammatory mediators; clinical neurophysiology and rehabilitation.

Contact

Thomas J. DeGraba, M.D. 301-295-0846
National Institute of Neurological Disorders and Stroke

Chronic Inflammatory Demyelinating Polyneuropathy

Eligibility Requirements

Patients with CIDP and demyelinating polyneuropathies associated with paraproteinemias.

Treatment/Procedures

Complete general and neurological examination; routine diagnostic studies; electromyography; pulmonary function tests; nerve biopsy; experimental therapeutic drug trials conducted in selected groups.

Contact

Marinos Dalakas, M.D. 301-496-9979
National Institute of Neurological Disorders and Stroke

Corpus Callosotomy

Eligibility Requirements

Patients who have done well after corpus callosotomy for seizures.

Treatment/Procedures

Physiological studies including EEG and transcranial magnetic stimulation; neuroimaging studies including PET and functional MRI.

Contact

Leonardo Cohen, M.D. via Quentis Scott 301-496-0600
National Institute of Neurological Disorders and Stroke

Corticobasal Degeneration

Eligibility Requirements

Patients ages 18 to 80 years old; no other major concurrent disease; capable of participating in cognitive studies.

Treatment/Procedures

Cognitive studies; mood state and personality evaluation; magnetic resonance imaging scan of the brain; neuropsychological evaluation; functional neuroimaging; neurological evaluation; neurophthalmological examination.

Contact

Jordan Grafman, Ph.D. 301-496-0220
National Institute of Neurological Disorders and Stroke

Dementia, Alzheimer's Disease

Eligibility Requirements

Patients ages 18 to 80 years old; no other major concurrent disease; capable of participating in cognitive studies.

Treatment/Procedures

Cognitive studies; mood state and personality evaluation; magnetic resonance imaging scan of the brain; neuropsychological evaluation; functional neuroimaging; neurological evaluation; neurophthalmological examination.

Contact

Jordan Grafman, Ph.D. 301-496-0220
National Institute of Neurological Disorders and Stroke

Dementia, Frontal Lobe/Pick's Disease

Eligibility Requirements

Patients ages 18 to 80 years old; no other major concurrent disease; capable of participating in cognitive studies.

Treatment/Procedures

Cognitive studies; mood state and personality evaluation; magnetic resonance imaging scan of the brain; neurological evaluation; neuropsychological evaluation; functional neuroimaging; neurophthalmological examination.

Contact

Jordan Grafman, Ph.D. 301-496-0220
National Institute of Neurological Disorders and Stroke

Diabetic Neuropathy

Eligibility Requirements

Selected patients with diabetic amyotrophy.

Treatment/Procedures

Complete general and neurological examination; electromyography and nerve biopsy for immunocytochemistry; suitable patients will undergo an immunotherapeutic drug study.

Contact

Marinos Dalakas, M.D. 301-496-9979

National Institute of Neurological Disorders and Stroke

Diabetic Neuropathy, Painful

Eligibility Requirements

Pain from distal symmetrical diabetic neuropathy, without serious cardiac disease; persistent pain despite a trial of a tricyclic antidepressant.

Treatment/Procedures

Experimental drugs for treatment of neuropathic pain, including blockers of excitatory NMDA receptors.

Contact

Christine Sang, M.D. 301-496-5483 x434

National Institute of Dental Research

Dystonia

Eligibility Requirements

Patients with generalized dystonia or focal dystonias including blepharospasm and writer's cramp.

Treatment/Procedures

Physiological studies including EMG, EEG, and transcranial magnetic stimulation; neuroimaging studies including PET and functional MRI. Some patients may be eligible for treatment protocols.

Contact

Barbara Karp, M.D. 301-496-0150

National Institute of Neurological Disorders and Stroke

Encephalitis, Viral

Eligibility Requirements

Patients ages 18 to 80 years old; no other major concurrent disease; capable of participating in cognitive studies.

Treatment/Procedures

Cognitive studies; mood state and personality evaluation; magnetic resonance imaging scan of the brain; neuropsychological evaluation; functional neuroimaging; neurological evaluation; neurophthalmological examination.

Contact

Jordan Grafman, Ph.D. 301-496-0220
National Institute of Neurological Disorders and Stroke

Epilepsy

Eligibility Requirements

Patients between 6 months and 80 years old with known or suspected seizure disorders.

Treatment/Procedures

Video-EEG monitoring; PET; MRI; TMS; experimental drug trials; surgery.

Contact

William H. Theodore, M.D. 301-496-1923
National Institute of Neurological Disorders and Stroke

Fabry Disease

Eligibility Requirements

Patients with, or suspected of having, Fabry disease.

Treatment/Procedures

Basic and clinical investigations. Enzyme replacement and gene therapy trials.

Contact

Roscoe O. Brady, M.D. 301-496-3285
Constance Kreps, R.N. 301-496-1465
Raphael Schiffmann, M.D. 301-496-1465
National Institute of Neurological Disorders and Stroke

Frontal Lobe Dysfunction/Dysexecutive Syndrome

Eligibility Requirements

Patients ages 18 to 80 years old; no other major concurrent disease; capable of participating in cognitive studies; primary problems in planning, reasoning, problem-solving, or social cognition.

Treatment/Procedures

Cognitive studies; mood state and personality evaluation; magnetic resonance imaging scan of the brain; neuropsychological evaluation; functional neuroimaging; neurological evaluation; neurophthalmological examination.

Contact

Jordan Grafman, Ph.D. 301-496-0220
National Institute of Neurological Disorders and Stroke

Gangliosidosis, Generalized (G_{M1})

Eligibility Requirements

Patients with, or suspected of having, generalized (G_{M1}) gangliosidosis.

Treatment/Procedures

Basic and clinical investigations.

Contact

Roscoe O. Brady, M.D. 301-496-3285
National Institute of Neurological Disorders and Stroke

Gaucher Disease

Eligibility Requirements

Patients with or without spleens having all types of Gaucher disease.

Treatment/Procedures

Enzyme replacement therapy, comprehensive evaluation of clinical status and laboratory manifestations in patients with Gaucher disease. Types 1 & 3; gene therapy, type 1; basic & clinical investigations, type 2.

Contact

Roscoe O. Brady, M.D. 301-496-3285
Constance Kreps, R.N. 301-496-1465
Raphael Schiffmann, M.D. 301-496-1465
National Institute of Neurological Disorders and Stroke

Gaucher Disease/Lysosomal Storage Disorders

Eligibility Requirements

Individuals with type 1, 2, or 3 Gaucher disease. Individuals with other lysosomal storage disorders (such as Fabry disease).

Treatment/Procedures

Comprehensive evaluation of clinical status and laboratory manifestations in patients with Gaucher disease. Individuals with other lysosomal disorders such as Fabry disease are also studied. Selected patients may qualify for participation in treatment protocols.

Contact

Kay Kuhns 301-496-0373
Ellen Sidransky, M.D. 301-496-0373
National Institute of Mental Health

Hemispherectomy

Eligibility Requirements

Patients who have done well after hemispherectomy for seizures.

Treatment/Procedures

Physiological studies including EEG and transcranial magnetic stimulation; neuroimaging studies including PET and functional MRI.

Contact

Leonardo Cohen, M.D. via Quentis Scott 301-496-0600
National Institute of Neurological Disorders and Stroke

Hyperekplexia, Startle Disease

Eligibility Requirements

Any patient with this disorder whether controlled by medication or not.

Treatment/Procedures

Physiological studies including several types of spinal reflexes.

Contact

Mary Kay Floeter, M.D., Ph.D. 301-496-7428 (FAX 301-402-8796)
National Institute of Neurological Disorders and Stroke

Ischemia, Cerebral

Eligibility Requirements

Patients with TIA, RIND, evolving and completed stroke; evaluation on outpatient basis.

Treatment/Procedures

Assessment with magnetic resonance (MR: conventional imaging, spectroscopy, diffusion, perfusion) to elucidate temporal neuroimaging profile of ischemia so as to identify viable ischemic tissue and assess prognosis.

Contact

Lucien Levy, M.D. 301-496-6801
National Institute of Neurological Disorders and Stroke

Krabbe Disease

Eligibility Requirements

Patients with, or suspected of having, Krabbe disease.

Treatment/Procedures

Basic and clinical investigations.

Contact

Roscoe O. Brady, M.D. 301-496-3285
Raphael Schiffmann, M.D. 301-496-1465
National Institute of Neurological Disorders and Stroke

Leukodystrophies, Childhood

Eligibility Requirements

Patients with leukodystrophies of suspected hereditary origin.

Treatment/Procedures

Basic and clinical investigations.

Contact

Raphael Schiffmann, M.D. 301-496-1465
Constance Kreps, R.N. 301-496-1465
National Institute of Neurological Disorders and Stroke

Menkes Disease, Early Copper Histidine Therapy

Eligibility Requirements

Patients with Menkes disease or Occipital Horn Syndrome. Affected newborn infants without neurological symptoms.

Treatment/Procedures

Copper replacement therapy, lumbar puncture, venipuncture, and skin biopsy.

Contact

Stephen G. Kaler, M.D. 301-496-4582

David S. Goldstein, M.D., Ph.D. 301-496-4582

National Institute of Neurological Disorders and Stroke

Mucopolipidosis IV

Eligibility Requirements

Patients with, or suspected of having, mucopolipidosis IV.

Treatment/Procedures

Basic and clinical investigations.

Contact

Raphael Schiffmann, M.D. 301-496-1465

Roscoe O. Brady, M.D. 301-496-3285

National Institute of Neurological Disorders and Stroke

Multiple Sclerosis

Eligibility Requirements

Patients with early disease or active progressive disease selected for immunologic studies, and for participation in clinical trials of experimental therapies.

Treatment/Procedures

Trials of experimental treatments conducted in selected patients; assessment of natural history of multiple sclerosis using magnetic resonance imaging (MRI).

Contact

Henry F. McFarland, M.D. 301-496-1801

National Institute of Neurological Disorders and Stroke

Multiple Sclerosis, Familial

Eligibility Requirements

Families with unequivocal occurrence of multiple sclerosis in more than one individual and in monozygotic and dizygotic twins who are discordant or concordant for MS.

Treatment/Procedures

Genetic, immunologic, and virologic studies.

Contact

Henry F. McFarland, M.D. 301-496-1801
National Institute of Neurological Disorders and Stroke

Myasthenia Gravis

Eligibility Requirements

Selected, medically stable patients with myasthenia gravis 6 to 12 months after thymectomy.

Treatment/Procedures

Complete general and neurological examination; electromyography and immunological evaluations; suitable patients undergo experimental therapeutic drug trial.

Contact

Marinos Dalakas, M.D. 301-496-9979
National Institute of Neurological Disorders and Stroke

Myoclonus

Eligibility Requirements

Patients with involuntary muscle jerks, either controlled with medications or uncontrolled.

Treatment/Procedures

Physiological studies including EEG and transcranial magnetic stimulation; neuroimaging studies including PET and functional MRI; opportunities available periodically for participation in protocols with new, experimental medications.

Contact

Mark Hallett, M.D. via Quentis Scott 301-496-0600
National Institute of Neurological Disorders and Stroke

Myopathies, Inflammatory

Eligibility Requirements

Patients with polymyositis, dermatomyositis or inclusion body myositis.

Treatment/Procedures

Complete general and neurological examination; routine diagnostic studies; electromyography; muscle biopsy; experimental therapeutic drug trials.

Contact

Marinos Dalakas, M.D. 301-496-9979

National Institute of Neurological Disorders and Stroke

Myopathies, Metabolic and Mitochondrial

Eligibility Requirements

Patients with various myopathies due to deficiency of a muscle enzyme and patients with mitochondrial diseases.

Treatment/Procedures

Enzymohistochemical and molecular genetic studies and examinations with magnetic resonance spectroscopy.

Contact

Marinos Dalakas, M.D. 301-496-9979

National Institute of Neurological Disorders and Stroke

Myopathies and Neuropathies, Undefined

Eligibility Requirements

Patients with unusual, acquired or hereditary neuromuscular diseases.

Treatment/Procedures

Enzymohistochemical, metabolic, morphological and immunocytochemical studies performed on muscle or nerve biopsies to define diagnosis; genetic counseling and advice on therapies.

Contact

Marinos Dalakas, M.D. 301-496-9979

National Institute of Neurological Disorders and Stroke

Neuralgia, Post-herpetic

Eligibility Requirements

Patients up to age 85 with pain persisting at least 2 months after an attack of shingles; patients must be cognitively intact and without serious medical disease.

Treatment/Procedures

Experimental drugs for the treatment of neuropathic pain, including blockers of excitatory NMDA receptors.

Contact

Mitchell Max, M.D. 301-496-5483
National Institute of Dental Research

Neurocardiologic Disorders (dysautonomia, neurocardiogenic syncope, reflex sympathetic dystrophy, hypernoradrenergic hypertension, orthostatic intolerance or baroreflex failure)

Eligibility Requirements

Adults with known or suspected abnormalities of neurocirculatory or catecholaminergic function.

Treatment/Procedures

Autonomic function testing; neurochemical assays; PET scanning; experimental, pathophysiologically rational therapy.

Contact

David S. Goldstein, M.D. 301-496-2103
National Institute of Neurological Disorders and Stroke

Neurodegenerative Disorders of Unknown Etiology

Eligibility Requirements

Patients with undiagnosed deterioration of the central and peripheral nervous systems.

Treatment/Procedures

Basic and clinical investigations; diagnostic testing.

Contact

Raphael Schiffmann, M.D. 301-496-1465
National Institute of Neurological Disorders and Stroke

Neurological Disorders Related to HTLV-I

Eligibility Requirements

Patients who have neurological disease and have positive serology for HTLV-I.

Treatment/Procedures

Patients with neurological disorders associated with HTLV-I infection are admitted for clinical and immunological evaluation; some experimental therapies considered.

Contact

Henry F. McFarland, M.D. 301-496-1801

National Institute of Neurological Disorders and Stroke

Neuromuscular Disorders, HIV-related

Eligibility Requirements

Patients with neuromuscular disorders related to HIV infection or due to various antiretroviral therapies.

Treatment/Procedures

Virological, immunological, toxicological, and therapeutic studies.

Contact

Marinos Dalakas, M.D. 301-496-9979

National Institute of Neurological Disorders and Stroke

Niemann-Pick Disease, Types A & B or C & D

Eligibility Requirements

Patients with types A and B or types C and D Niemann-Pick disease.

Treatment/Procedures

Basic and clinical investigations; identification and cloning of involved gene(s).

Contact

Raphael Schiffmann, M.D. 301-496-1465

Roscoe O. Brady, M.D. 301-496-3285

Peter G. Pentchev, Ph.D. 301-496-7100

National Institute of Neurological Disorders and Stroke

Occipital Horn Syndrome

See *Menkes Disease*.

Palsy, Progressive Supranuclear

Eligibility Requirements

Patients ages 18 to 80 years old; no other major concurrent disease; capable of participating in cognitive studies.

Treatment/Procedures

Cognitive studies; mood state and personality evaluation; magnetic resonance imaging scan of the brain; neuropsychological evaluation; functional neuroimaging; neurological evaluation; neurophthalmological examination.

Contact

Jordan Grafman, Ph.D. 301-496-0220
National Institute of Neurological Disorders and Stroke

Paralysis, Periodic and Channel Disorders

Eligibility Requirements

Patients with periodic paralysis.

Treatment/Procedures

Experimental therapeutic drug trials.

Contact

Marinos Dalakas, M.D. 301-496-9979
National Institute of Neurological Disorders and Stroke

Parkinson's Disease

Eligibility Requirements

Patients in good physical health with motor slowing and good cognitive function.

Treatment/Procedures

Physiological studies of the motor disorder including transcranial magnetic stimulation and neuroimaging procedures; advanced patients with freezing could be considered for program of experimental surgery.

Contact

Mark Hallett, M.D. via Quentis Scott 301-496-0600
National Institute of Neurological Disorders and Stroke

Parkinson's Disease

Eligibility Requirements

Patients ages 18 to 80 years old; no other major concurrent disease; capable of participating in cognitive studies.

Treatment/Procedures

Cognitive studies; mood state and personality evaluation; magnetic resonance imaging scan of the brain; neuropsychological evaluation; functional neuroimaging; neurological evaluation; neurophthalmological examination.

Contact

Jordan Grafman, Ph.D. 301-496-0220
National Institute of Neurological Disorders and Stroke

Parkinson's Disease

Eligibility Requirements

Patients with Parkinson's disease at any stage (early untreated to advanced with response complications) and no other major medical illness.

Treatment/Procedures

Drug therapies, including novel neuroprotective trials in early to moderate patients; new dopamine agonist; NMDA receptor agonist for stable and fluctuating patients; estrogen study for postmenopausal females.

Contact

Marjorie Gillespie, R.N. 301-496-4604
National Institute of Neurological Disorders and Stroke

Parkinson's Disease

Eligibility Requirements

Patients 18 to 80 years old with Parkinson's disease or related disorders with Parkinsonian features.

Treatment/Procedures

Neurological evaluation; PET scan; MRI scan.

Contact

Allen R. Braun, M.D. 301-402-1497
National Institute on Deafness and Other Communication Disorders

Pituitary Tumors

Eligibility/Requirements

Patients with microadenomas as well as larger pituitary lesions.

Treatment/Procedures

Endocrinological investigation and surgery.

Contact

Edward H. Oldfield, M.D. 301-496-2921

National Institute of Neurological Disorders and Stroke

Polymyositis, Dermatomyositis, and Inclusion Body Myositis

See *Myopathies, Inflammatory*.

Post Polio Syndrome and Other Related Motor Neuron Diseases

Eligibility Requirements

Patients with post polio syndrome and other related motor neuron diseases.

Treatment/Procedures

Clinical, electrophysiological, histological, immunological and virological evaluation; experimental therapeutic drug trials conducted in selected groups.

Contact

Marinos Dalakas, M.D. 301-496-9979

National Institute of Neurological Disorders and Stroke

Seizures

See *Epilepsy*.

Spinal, Arteriovenous Malformations

Eligibility Requirements

Patients with known or suspected spinal arteriovenous malformation.

Treatment/Procedures

Diagnostic angiography and surgery.

Contact

Edward H. Oldfield, M.D. 301-496-2921

National Institute of Neurological Disorders and Stroke

Spinal Tumors

Eligibility Requirements

Patients with Symptomatic Vertebral Hemangioma or recurrent spinal metastasis.

Treatment/Procedures

Diagnostic angiography and intramural ethanol injection.

Contact

Edward H. Oldfield, M.D. 301-496-2921

National Institute of Neurological Disorders and Stroke

Stiff-person Syndrome

Eligibility Requirements

Patients 18 to 80 years old with stiff-person syndrome and anti-GAD antibodies.

Treatment/Procedures

Experimental double-blind study with immunotherapy.

Contact

Marinos C. Dalakas, M.D. 301-496-9979

National Institute of Neurological Disorders and Stroke

Stroke

Eligibility Requirements

Patients who are able to communicate, with a single stroke giving rise to weakness or paralysis of the arm which has recovered.

Treatment/Procedures

Physiological studies of recovery process including neuroimaging and transcranial magnetic stimulation; opportunities to participate in program of rehabilitation.

Contact

Leonardo Cohen, M.D. via Quentin Scott 301-496-0600

Eric M. Wassermann

National Institute of Neurological Disorders and Stroke

Stroke

Eligibility Requirements

Patients ages 18 to 80 years old; no other major concurrent disease; capable of participating in cognitive studies.

Treatment/Procedures

Cognitive studies; mood state and personality evaluation; magnetic resonance imaging scan of the brain; neuropsychological evaluation; functional neuroimaging; neurological evaluation; neurophthalmological examination.

Contact

Jordan Grafman, Ph.D. 301-496-0220
National Institute of Neurological Disorders and Stroke

Sydenham's Chorea

Eligibility Requirements

Boys and girls 3 to 16 years old with a new onset of Sydenham's chorea (within 2 months).

Treatment/Procedures

Controlled treatment trial comparing prednisone, plasma exchange, and intravenous immunoglobulin (IVIG) to expedite recovery.

Contact

Marjorie Garvey, M.D. 301-496-5323
National Institute of Mental Health

Syringomyelia

Eligibility Requirements

Patients with untreated or progressive syringomyelia.

Treatment/Procedures

Investigation and surgery.

Contact

Edward H. Oldfield, M.D. 301-496-2921
National Institute of Neurological Disorders and Stroke

Tay-Sachs Disease

Eligibility Requirements

Patients with, or suspected of having, Tay-Sachs disease.

Treatment/Procedures

Basic and clinical investigations.

Contact

Roscoe O. Brady, M.D. 301-496-3285

Raphael Schiffmann, M.D. 301-496-1465

National Institute of Neurological Disorders and Stroke

Tourette's Syndrome

Eligibility Requirements

Patients 18 to 80 years old with Tourette's syndrome; vocal and/or motor tics at present.

Treatment/Procedures

Neurological evaluation; PET scan; MRI scan.

Contact

Allen R. Braun, M.D. 301-402-1497

National Institute on Deafness and Other Communication Disorders

Tourette's Syndrome (tics)

Eligibility Requirements

Adult patients with Tourette's syndrome or motor tics.

Treatment/Procedures

Physiological studies including EEG and transcranial magnetic stimulation.

Contact

Barbara Karp, M.D. 301-496-0150

National Institute of Neurological Disorders and Stroke

Tremor

Eligibility Requirements

Patients with essential tremor or other tremors without significant other neurological disease.

Treatment/Procedures

Physiological studies including EEG and transcranial magnetic stimulation; neuroimaging studies including PET and functional MRI. Patients with other family members involved may enroll in genetic studies.

Contact

Mark Hallett, M.D. via Quentis Scott 301-496-0600
National Institute of Neurological Disorders and Stroke

Urbach-Wiethe Disease/Lipid Proteinosis

Eligibility Requirements

Diagnosis of Urbach-Wiethe disease (lipid proteinosis) without other concurrent disease. Patients ages 18 to 80 years old capable of participating in cognitive studies. CT or MRI evidence of selective unilateral or bilateral structural damage to the amygdala.

Treatment/Procedures

Cognitive studies; mood state and personality evaluation; magnetic resonance imaging scan of the brain; neuropsychological evaluation; functional neuroimaging; neurological evaluation; neuroophthalmological evaluation.

Contact

Jordan Grafman, Ph.D. 301-496-0220
National Institute of Neurological Disorders and Stroke

Visual Attention/Neglect, Impaired

Eligibility Requirements

Patients ages 18 to 80 years old; no other major concurrent disease; capable of participating in cognitive studies; primary problems in visual attention to spatial location.

Treatment/Procedures

Cognitive studies; mood state and personality evaluation; magnetic resonance imaging scan of the brain; neuropsychological evaluation; functional neuroimaging; neurological evaluation; neuroophthalmological examination.

Contact

Jordan Grafman, Ph.D. 301-496-0220
National Institute of Neurological Disorders and Stroke

Pediatric Disorders

Carney Complex/Primary Pigmented Adrenocortical Dysplasia (PPNAD)

Eligibility Requirements

Sporadic or familial cases of patients with Carney Complex and/or PPNAD.

Treatment/Procedures

DNA studies; surgical treatment (adrenalectomy if needed).

Contact

Constantine A. Stratakis, M.D. 301-496-4686

National Institute of Child Health and Human Development

Cystinosis

Eligibility Requirements

Positive diagnosis of nephropathic, juvenile, or benign cystinosis (pre-transplant or post-transplant).

Treatment/Procedures

Examination of clinical characteristics; treatment with cysteamine; investigation of defective gene.

Contact

William A. Gahl, M.D., Ph.D. 301-496-9101

National Institute of Child Health and Human Development

Hermansky-Pudlak Syndrome

Eligibility Requirements

Positive diagnosis.

Treatment/Procedures

Clinical characterization of disorder; investigation into basic defect; skin biopsy for cell culture.

Contact

William A. Gahl, M.D., Ph.D. 301-496-9101

National Institute of Child Health and Human Development

Hypoparathyroidism, Parathyroid Disease

Eligibility Requirements

Patients with hypoparathyroidism ages 4 to 65 years old without significant renal or liver insufficiency.

Treatment/Procedures

Treatment with subcutaneous parathyroid hormone for 6 months, then randomized to either PTH or conventional therapy (Rocaltrol) for long-term outpatient follow-up.

Contact

Karen K. Winer, M.D.

Gordon B. Cutler Jr., M.D. 301-496-4686

National Institute of Child Health and Human Development

Lysosomal Storage Disorders of Unknown Etiology

Eligibility Requirements

Strong clinical evidence of lysosomal storage; known lysosomal disorders eliminated.

Treatment/Procedures

Skin biopsy for basic research.

Contact

William A. Gahl, M.D., Ph.D. 301-496-9101

National Institute of Child Health and Human Development

Male Pseudohermaphroditism-5-alpha Reductase (Type 2) Deficiency

Eligibility Requirements

Adult males suspected of having male pseudohermaphroditism due to 5-alpha reductase deficiency based on clinical findings and a testosterone/DHT ratio greater than 16.

Treatment/Procedures

Administration of topical dihydrotestosterone cream for 6 months. Evaluation of penis and prostate size, body composition, bone density and turnover, hormonal profiles, and psychological responses.

Contact

Frank Czerwiec, M.D., Ph.D. or Michael Collins, M.D. 301-496-4686

National Institute of Child Health and Human Development

Osteogenesis Imperfecta

Eligibility Requirements

Infants and toddlers with suspected type II, III or IV osteogenesis imperfecta; skin biopsy should **not** have been done.

Treatment/Procedures

Skin biopsy; genetic workup; examination of clinical characteristics over time; aggressive physical therapy; bracing; study of growth deficiency.

Contact

Elizabeth Hopkins, Research Nurse 301-496-0741
National Institute of Child Health and Human Development

Pituitary Tumors, Cushing Syndrome in Children

Eligibility Requirements

Children and adolescents with any kind of pituitary tumors, including craniopharyngiomas, Cushing disease, acromegaly and prolactinomas.

Treatment/Procedures

Evaluation of the tumor(s), treatment with medicine(s), surgery and/or irradiation, genetic studies.

Contact

Constantine A. Stratakis, M.D. 301-496-4686
National Institute of Child Health and Human Development

Prader-Willi Syndrome

Eligibility Requirements

Children and adolescents with Prader-Willi syndrome.

Treatment/Procedures

Evaluation of hypothalamic-pituitary-growth hormone axis function; treatment with hexarelin, a growth hormone-releasing hormone analogue.

Contact

Constantine A. Stratakis, M.D. 301-496-4686
National Institute of Child Health and Human Development

Precocious Puberty, Familial Male (FMPP)

Eligibility Requirements

Familial male precocious puberty with bone age \leq 14 years.

Treatment/Procedures

Treatment with an antiandrogen (spironolactone) and two aromatase inhibitors (testolactone and fadrozole) to compare their safety and efficacy.

Contact

Ellen Leschek, M.D. 301-496-4686

National Institute of Child Health and Human Development

Precocious Puberty, McCune Albright Syndrome

Eligibility Requirements

Girls less than 10 years of age with confirmed diagnosis of gonadotropin-independent precocious puberty.

Treatment/Procedures

Investigational drug therapy with an aromatase enzyme inhibitor.

Contact

Susan B. Nunez, M.D. 301-496-6153

National Institute of Child Health and Human Development

Sexual Abuse, Child

Eligibility Requirements

Children aged 3 to 13 years who have made allegations of sexual abuse or are suspected to be victims.

Treatment/Procedures

Assessment of forensic interviews and investigative procedures relative to developmental issues. Verbatim transcripts of interviews are necessary.

Contact

Michael E. Lamb, Ph.D. 301-496-0420

National Institute of Child Health and Human Development

Short Stature and Stress

Eligibility Requirements

Children and adolescents with short stature and evidence for anxiety and stress behaviors.

Treatment/Procedures

Growth hormone-stimulation studies; evaluation of hypothalamic-pituitary-adrenal axis function; measurements of anxiety and stress behaviors.

Contact

Constantine Stratakis, M.D. 301-496-4686

National Institute of Child Health and Human Development

Psychiatric Disorders/Behavioral Disorders

Alzheimer's Disease/Dementia of the Alzheimer's Type

Eligibility Requirements

Patients should have a diagnosis of mild to moderate dementia and be in good general health.

Treatment/Procedures

After a thorough diagnostic evaluation with cognitive, physiologic and brain imaging studies, patients may be offered further research diagnostic tests and short- and long-term treatment studies with investigational agents. Long-term follow-up is available in collaboration with local primary physicians.

Contact

K. Sue Bell, M.S.W. 301-496-5111 or 496-0948
National Institute of Mental Health

Alzheimer's Disease/Family Member Study

Eligibility Requirements

Adults must be over the age of 50 years and normal cognitively but have at least one first degree relative (sister, brother, or parent) with dementia of the Alzheimer's type.

Treatment/Procedures

After a careful baseline evaluation, subjects will be tested with a series of genetic markers, brain imaging tests, possible medication tests, and a cognitive battery. Follow-up studies will be offered on a yearly basis.

Contact

Judy Friz, M.A. 301-496-0948
National Institute of Mental Health

Anxiety Disorders (Panic Disorder, Social Phobia, Post Traumatic Stress Disorder)

Eligibility Requirements

Adults between the ages of 18 and 65 in good general health. For most research protocols, subjects are asked to be withdrawn from medication prior to entering a study.

Treatment/Procedures

Medications, repeated transcranial magnetic stimulation (rTMS), neuroimaging, genetic studies.

Contact

Marilla Geraci, R.N. 301-496-6565 (Panic Disorder, Social Phobia)
Christina Morgan, B.A. 301-496-4874 (Post Traumatic Stress Disorder)
National Institute of Mental Health

Attention-deficit/Hyperactivity Disorder

Eligibility Requirements

Children 6 to 12 years old with Attention-Deficit/Hyperactivity Disorder (ADHD), with IQ>80, and no serious medical conditions for day program study; and families with at least two full siblings with ADHD for genetic study.

Treatment/Procedures

Day Program: Three-month highly structured comprehensive program that includes medical, neurological and psychiatric evaluations, psychological testing, and magnetic resonance imaging during attendance at the NIH school; includes recreational therapy and social skills training; involves a double-blind study of three stimulant medications—Dexedrine, Dexedrine Spansule, and Adderall—as well as placebo; test results and recommendations provided at discharge conference with parents and school officials at program's end.

Genetic Study: Outpatient visits to NIH for blood test, psychiatric evaluation, and computer testing. Possible magnetic resonance imaging and psychological testing.

Contact

Wendy Sharp, M.S.W. 301-496-0851
National Institute of Mental Health

Attention-deficit Hyperactivity Disorder

Eligibility Requirements

Two or more siblings (or related family members) under the age of 18 who have ADHD.

Treatment/Procedures

Psychological and cognitive testing; research bloods drawn for genetic analyses.

Contact

Alan Zametkin, M.D. 301-496-4707
National Institute of Mental Health

Bereavement/Grief

Eligibility Requirements

Adults over 50 years old in good general health who have suffered the death of their spouse *within the past one to three months*.

Treatment/Procedures

After a screening evaluation, patients will be tested with a series of biochemical, cognitive, imaging, and immunologic studies initially, and then followed monthly for 13 months after spousal death. Patients will be offered treatment if depression occurs.

Contact

Larry Bauer, R.N. 301-496-6565 or 301-496-0948
National Institute of Mental Health

Bipolar Disorder (Inpatient)

Eligibility Requirements

Patients at least 18 years old with bipolar illness type I and II, including ultra rapid cycling (episodes lasting a week or less) and ultra-ultra rapid cycling (distinct dramatic mood shifts between hypomania and depression within a 24-hour period).

Treatment/ Procedures

Drug studies of the newer anticonvulsants and antidepressants, calcium channel blockers, thyroid potentiation and rTMS. Studies of CSF metabolites and peptides, brain imaging with PET and functional MRI studies including regional cerebral blood flow correlates of spontaneous and drug-induced clinical changes in mood disorders. Life charting and neuropsychiatric evaluation.

Contact

Gabriele S. Leverich, M.S.W., L.C.S.W.-C. 301-496-7180 or 301-435-3625
National Institute of Mental Health

Bipolar Disorder (Outpatient)

Eligibility Requirements

Patients at least 18 years old with bipolar illness type I and II, including ultra and ultra-ultra rapid cycling, and patients with major depression, recurrent. For the NIMH/Stanley Foundation Bipolar Network Studies, patients with schizoaffective disorder, bipolar type, are also considered.

Treatment/ Procedures

Drug studies of the newer anticonvulsants, including gabapentin and lamotrigine, antidepressants, rTMS, thyroid potentiation and calcium channel blockers, CSF studies and brain imaging with PET and MRI studies. Some outpatient studies require a brief evaluative inpatient stay. Life charting and neuropsychiatric evaluations.

Contact

Gabriele S. Leverich, M.S.W., L.C.S.W.-C. 301-496-7180 or 301-435-3625
National Institute of Mental Health

Bipolar Disorder, Rapid Cycling

Eligibility Requirements

Patients may be medicated or drug free and must have four or more affective episodes per year including one depression and one hypomania or mania. Patients remain outpatients and in treatment with their referring physician.

Treatment/Procedures

Experimental treatments are tested, including light therapy, negative ion generators. Some studies involve brief hospitalizations (overnight or one to two days) for chronobiological evaluation. The causes of rapid cycling bipolar disorder are studied, with emphasis on the role that disrupted circadian rhythms and female gender may play.

Contact

Lauren Weinstock 301-496-5323
National Institute of Mental Health

Bipolar Affective Disorder (Genetic Study)

Eligibility Requirements

Individuals with bipolar affective disorder (manic-depressive illness) having several other family members also affected with bipolar disorder or recurrent depression.

Treatment/Procedures

Studies are conducted to identify genetic factors that may influence susceptibility to bipolar affective disorder. Participation requires a blood sample and may include a diagnostic interview.

Contact

Kay Kuhns 301-496-0373
Edward I. Ginns, M.D., Ph.D. 301-496-0373
National Institute of Mental Health

Bipolar Disorder, Genetic Study

Eligibility Requirements

Siblings with bipolar disorder and with living parents.

Treatment/Procedures

Each participant gives an interview and a blood sample. No travel is needed.

Contact

Liz Maxwell, L.C.S.W. 301-496-8977
National Institute of Mental Health

Climacteric Perimenopause-related Dysphoria/Depression

See *Reproductive Endocrine Disorders*.

Depression, Bone Density Decrease

Eligibility Requirements

Women and men, ages 18 to 65 years old, who have a history of depressive illness and no medical diseases. It is not necessary to be currently depressed.

Treatment/Procedures

Bone density assessment, hormonal and psychiatric evaluation.

Contact

Paulo J. Negro, Jr., M.D., M.Ph. 301-496-8928
National Institute of Mental Health

Depression, Brain Imaging

Eligibility Requirements

Women and men, 18 to 65 years old with current (unipolar or bipolar) depression, off medications. No medical problems.

Treatment/Procedures

PET scan of the brain; MRI of the brain; psychological testing/hormonal and psychiatric evaluation.

Contact

Paulo J. Negro, Jr., M.D., M.Ph. 301-496-8928
National Institute of Mental Health

Depression, Chronic Fatigue, Fibromyalgia, Cytokines and Immune Function

Eligibility Requirements

Women and men, ages 18 to 65 years old.

Treatment/Procedures

Blood draws for measurement of cytokines and evaluation of immune function.

Contact

Denise Sciuлло, M.D. 301-496-6978
National Institute of Mental Health

Depression, Climacteric Perimenopause-related Dysphoria**Eligibility Requirements**

Women in perimenopause/menopause and men ages 45 and older who are experiencing depressive symptoms. Must be in good physical health and medication free.

Treatment/Procedures

Hormonal evaluation; treatment.

Contact

Linda Simpson-St. Clair, R.N. 301-496-9576
National Institute of Mental Health

Depression/Dsyphoria-Recurrent Brief**Eligibility Requirements**

Women 18 to 45 years old with recurrent brief episodes of depressive symptoms; subjects must be free of other medical problems and taking no medications.

Treatment/Procedures

Hormonal evaluation; treatment.

Contact

Linda Simpson-St. Clair, R.N. 301-496-9576
National Institute of Mental Health

Depression, Geriatric (Late-Onset)**Eligibility Requirements**

Elderly patients who either currently have major depressive disorder or who have had serious depression in the past. Of particular interest are those subjects who have developed depression for the first time late in life with or without cognitive symptoms (late-onset depression).

Treatment/Procedures

After a careful baseline evaluation, subjects will be tested with a series of genetic markers, brain imaging tests, possible medication tests, and a cognitive battery, and will then enter a longitudinal study of depression. Follow-up studies will be offered on a yearly basis. Care will be continued by the local primary physician.

Contact

K. Sue Bell, M.S.W. 301-496-5111 or 496-0948
National Institute of Mental Health

Depression, Hormonal Changes and Exercise

Eligibility Requirements

Women and men, ages 18 to 55 years old, who are currently depressed and medication-free.

Treatment/Procedures

Two exercise sessions on a treadmill and hormonal evaluation; treatment available for some subjects.

Contact

Andre Negrao, M.D. 301-496-0857
National Institute of Mental Health

Depression, Hormonal Changes with Atypical or Melancholic Features

Eligibility Requirements

Women and men, ages 18 to 55 years old, who are currently experiencing episodes of major depression with disturbances in appetite, sleep and mood.

Treatment/Procedures

Admission to a research unit for an intensive hormonal evaluation or outpatient study at a metabolic unit.

Contact

Denise Sciuillo, M.D. 301-496-6978
Sara Avery, R.N. 301-496-6565 ext 212
National Institute of Mental Health

Depression-Postpartum

See *Reproductive Endocrine Disorders*.

Depression, Seasonal Affective Disorder (Winter Type)

Eligibility Requirements

Medically healthy patients age 18-65 who experience recurrent seasonal depression in fall and winter; must be within commuting distance to the NIH for most studies.

Treatment/Procedures

Light treatment (phototherapy) and the relationship between mood and changes in the seasons and climate are studied. The course of seasonal affective disorder and its relationship to seasonal changes in secretion of the hormone melatonin, are of particular interest. Selected patients may participate in short- or long-term studies.

Contact

Ron Barnett, Ph.D. 301-496-0500
Holly Lowe, L.C.S.W.-C. 301-496-7427
National Institute of Mental Health

Depression and Dysthymic Disorder, Magnetic Resonance of the Brain

Eligibility Requirements

Women and men, ages 18 to 65 years old, who have a history of depressive illness and no medical diseases.

Treatment/Procedures

MRI of the brain, psychiatric, medical, hormonal, neuropsychological evaluation. Follow-up within one year. Treatment available for some subjects.

Contact

Paulo J. Negro, M.D., M.Ph. 301-496-8928
National Institute of Mental Health

Drug-Induced Neuropsychiatric Illnesses (Ecstasy/MDMA); Fenfluramine, Dexfenfluramine

Eligibility Requirements

Patients between the ages of 18 and 65 in good general health, who have used any of several amphetamine analogs including MDMA ("Ecstasy"), fenfluramine, dexfenfluramine or related drugs.

Treatment/Procedures

Procedures vary depending upon which drug was used, but could include a 5-day inpatient study and a variety of psychological and biological tests that evaluate serotonin function.

Contact

Victoria Eligulashvili, B.S. 301-496-4874
National Institute of Mental Health

Fragile X Disorder

Eligibility Requirements

Females over the age of 18 who have fragile X disorder.

Treatment/Procedures

Positron emission tomography scans.

Contact

Alan Zametkin, M.D. 301-496-4707
National Institute of Mental Health

Gaucher Disease/Lysosomal Storage Disorders

Eligibility Requirements

Individuals with type 1, 2, or 3 Gaucher disease. Individuals with other lysosomal storage disorders (such as Fabry disease).

Treatment/Procedures

Comprehensive evaluation of clinical status and laboratory manifestations in patients with Gaucher disease. Individuals with other lysosomal disorders such as Fabry disease are also studied. Selected patients may qualify for participation in treatment protocols.

Contact

Kay Kuhns 301-496-0373
Ellen Sidransky, M.D. 301-496-0373
National Institute of Mental Health

Male Pseudohermaphroditism-5-alpha Reductase Deficiency (Type 2)

See Reproductive Endocrine Disorders.

Obesity and Depression, Hormonal Changes

Eligibility Requirements

Women and men, 18 to 55 years old, who are currently overweight and have episodes of major depression with disturbances in appetite, sleep, and mood.

Treatment/Procedures

Admission to a research unit for an intensive hormonal evaluation or outpatient study at a metabolic unit.

Contact

Denise Sciallo, M.D. 301-496-6978
Sara Avery, R.N. 301-496-6565 ext. 212
National Institute of Mental Health

Obsessive Compulsive Disorder

Eligibility Requirements

Boys and girls, ages 5 to 12, with 1) recent onset, or 2) acute exacerbation, or 3) episodic course of OCD or tics/Tourette's disorder, if associated with a preceding streptococcal infection.

Treatment/Procedures

1. Controlled treatment trial comparing plasma exchange, intravenous immunoglobulin (IVIG) and placebo (sham IVIG).
2. Double-blind placebo controlled trial of penicillin prophylaxis to prevent strep-associated symptom exacerbations. Outpatient.
3. Double-blind placebo controlled trial of amoxicillin for strep-associated symptoms. Outpatient.

Contact

Lorraine Lougee, L.C.S.W.-C. or Molly Henry 301-496-5323
National Institute of Mental Health

Obsessive Compulsive Disorder in Adults

Eligibility Requirement

Adults ages 18 and older with current symptoms of obsessive compulsive disorder. Outpatient study.

Treatment/Procedures

Diagnostic evaluation; genetic studies; transcranial magnetic stimulation brain imaging; trials of novel treatment agents (e.g., controlled trial of gabapentin).

Contact

Yung-Mei Leong 301-496-3421
National Institute of Mental Health

Panic Disorder, Genetic Study

Eligibility Requirements

Siblings with panic disorder and with living parents.

Treatment/Procedures

Each participant gives an interview and a blood sample. No travel is needed.

Contact

Liz Maxwell, L.C.S.W. 301-496-8977
National Institute of Mental Health

Premenstrual Syndrome

See *Reproductive Endocrine Disorders*.

Schizophrenia, Childhood Onset

Eligibility Requirements

Boys and girls ages 6 to 18 years old with onset of hallucinations and delusions by age 12; IQ>70; no serious neurological or medical disorders.

Treatment/Procedures

One- to four-month inpatient stay; thorough evaluation; optional participation in drug trials.

Contact

Marge Lenane, L.C.S.W. 301-496-7962
National Institute of Mental Health

Schizophrenia

Eligibility Requirements

Physically healthy adults who are competent to give informed consent; no mental retardation; no current significant risk of violent behavior to self or others; no extensive abuse of street drugs or alcohol.

Treatment/Procedures

Inpatient study with neuropsychiatric evaluation, neuropsychological testing, medication treatment studies (including clozapine, risperidone and olanzapine), neuroimaging studies and clinical treatment including occupational and recreational therapy, family education and sheltered work placement.

Contact

Kathleen O'Leary 202-373-6068 or toll free at 1-888-674-6464
National Institute of Mental Health

Schizophrenia, Sibling Study

Eligibility Requirements

Adult who has a clear diagnosis of schizophrenia and is competent to give informed consent plus a full sibling with or without a psychiatric diagnosis.

Treatment/Procedures

Two days of outpatient procedures including a blood sample, 2 MRI neuroimaging scans, a neurological exam, psychological testing and interviews. Parents will be asked to send blood samples. Travel and lodging are provided and participants are paid.

Contact

Mary Weirich, M.S.W. 202-373-6179 or toll free at 888-NRH-NIMH
National Institute of Mental Health

Schizophrenia/Schizoaffective Disorder

Eligibility Requirements

Patients 18 to 65 years old with a diagnosis of schizophrenia/schizoaffective disorder; in good physical health and willing to participate in study; inpatient or outpatient.

Treatment/Procedures

1. Studies of novel and new antipsychotic medications; infusion and neuroimaging studies of biochemical probes of schizophrenia; effects of medications on receptor occupancy and cognitive performance; participation in studies includes diagnostic evaluation and linkage with community resources.

Contact

Rachel Hayden, L.C.S.W.-C. 301-496-7128

Pam Holmes, L.C.S.W.-C. 301-496-7128

National Institute of Mental Health

Schizophrenia, Genetic Study

Eligibility Requirements

Adult individuals with a diagnosis of schizophrenia or schizoaffective disorder and both parents. If both parents are not available, one parent and one sibling may participate.

Treatment/Procedures

A small blood sample will be collected from the participants. The individual with schizophrenia or schizoaffective disorder will participate in a diagnostic interview and rating of symptoms. No travel required.

Contact

Kayleen Hadd, R.N., M.S.N. 301-496-2082

National Institute of Mental Health

Schizophrenia, Genetic Study

Eligibility Requirements

Families with one or more siblings with schizophrenia and with living parents.

Treatment/Procedures

Telephone interview and small blood sample. No need for travel. Stipend will be paid.

Contact

Pablo Gejman, M.D. 301-496-8977

National Institute of Mental Health

Sydenham's Chorea

Eligibility Requirements

Boys and girls 3 to 16 years old with a new onset of Sydenham's chorea (within 2 months).

Treatment/Procedures

Controlled treatment trial comparing prednisone, plasma exchange, and intravenous immunoglobulin (IVIG) to expedite recovery.

Contact

Lorraine Lougee, L.C.S.W.-C. or Molly Henry 301-496-5323
National Institute of Mental Health

Tourette's Disorder

Eligibility Requirements

Boys and girls, ages 5 to 12, with 1) recent onset, or 2) acute exacerbation, or 3) episodic course of OCD or tics/Tourette's disorder, if associated with a preceding streptococcal infection.

Treatment/Procedures

1. Controlled treatment trial comparing plasma exchange, intravenous immunoglobulin (IVIG) and placebo (sham IVIG).
2. Double blind placebo controlled trial of penicillin prophylaxis to prevent strep-associated symptom exacerbations. Outpatient.
3. Double-blind placebo controlled trial of amoxicillin for strep-associated symptoms. Outpatient.

Contact

Lorraine Lougee, L.C.S.W.-C. or Molly Henry 301-496-5323
National Institute of Mental Health

Unipolar Disorder (Inpatient and Outpatient)

Eligibility Requirements

Patients at least 18 years old with major depression, recurrent, accepted for inpatient and outpatient studies.

Treatment/ Procedures

Drug studies of the newer anticonvulsants and antidepressants, calcium channel blockers, thyroid potentiation and rTMS. Studies of CSF metabolites and peptides, brain imaging with PET and functional MRI studies including regional cerebral blood flow correlates of spontaneous and drug-induced clinical changes in mood disorders. Life charting and neuropsychiatric evaluation.

Contact

Gabriele S.Leverich, M.S.W., L.C.S.W.-C. 301-496-7180 or 301-435-3625
National Institute of Mental Health

Pulmonary Diseases

Alpha 1-Antitrypsin Deficiency

Eligibility Requirements

Patients with known or suspected diagnosis of alpha 1-antitrypsin deficiency.

Treatment/Procedures

Diagnosis and evaluation of the activity of the disease by genetic testing, pulmonary function testing (breathing tests), methacholine breathing test, bronchoalveolar lavage (lung washings), drug trials for replacement therapy.

Contact

Joel Moss, M.D., Ph.D. 301-496-3632
National Heart, Lung, and Blood Institute

Asthma

Eligibility Requirements

Patients with known or suspected diagnosis of asthma.

Treatment/Procedures

Diagnosis and evaluation of the activity of the disease by genetic testing, pulmonary function testing (breathing tests) and bronchoalveolar lavage (lung washings).

Contact

Joel Moss, M.D., Ph.D. 301-496-3632
National Heart, Lung, and Blood Institute

Bronchitis, Chronic

Eligibility Requirements

Patients with diagnosis of chronic bronchitis.

Treatment/Procedures

Diagnosis and evaluation of the activity of the disease by genetic testing, pulmonary function testing (breathing tests) and bronchoalveolar lavage (lung washings).

Contact

Joel Moss, M.D., Ph.D. 301-496-3632
National Heart, Lung, and Blood Institute

Collagen Vascular Disorders

Eligibility Requirements

Patients with known or suspected pulmonary manifestations of collagen vascular disorders.

Treatment/Procedures

Diagnosis and evaluation of the activity of the disease by genetic testing, pulmonary function testing (breathing tests), bronchoalveolar lavage (lung washings) or possibly open lung biopsy.

Contact

Joel Moss, M.D., Ph.D. 301-496-3632
National Heart, Lung, and Blood Institute

Cystic Fibrosis

Eligibility Requirements

Adult patients with known diagnosis of cystic fibrosis.

Treatment/Procedures

Evaluation of the activity of the disease by genetic testing, pulmonary function testing (breathing tests) and bronchoalveolar lavage (lung washings).

Contact

Joel Moss, M.D., Ph.D. 301-496-3632
National Heart, Lung, and Blood Institute

Emphysema

Eligibility Requirements

Patients with diagnosis of emphysema.

Treatment/Procedures

Diagnosis and evaluation of the activity of the disease by genetic testing, pulmonary function testing (breathing tests) and bronchoalveolar lavage (lung washings).

Contact

Joel Moss, M.D., Ph.D. 301-496-3632
National Heart, Lung, and Blood Institute

Histiocytosis X

Eligibility Requirements

Patients with known or suspected diagnosis of histiocytosis X.

Treatment/Procedures

Diagnosis and evaluation of the activity of the disease by genetic testing, pulmonary function testing (breathing tests), bronchoalveolar lavage (lung washings) or possible open lung biopsy.

Contact

Joel Moss, M.D., Ph.D. 301-496-3632
National Heart, Lung, and Blood Institute

Hypersensitivity Pneumonitis

Eligibility Requirements

Patients with known or suspected diagnosis of hypersensitivity pneumonitis.

Treatment/Procedures

Diagnosis and evaluation of the activity of the disease by genetic testing, pulmonary function testing (breathing tests), bronchoalveolar lavage (lung washings) or possibly open lung biopsy.

Contact

Joel Moss, M.D., Ph.D. 301-496-3632
National Heart, Lung, and Blood Institute

Idiopathic Pulmonary Fibrosis

Eligibility Requirements

Patients with known or suspected diagnosis of idiopathic pulmonary fibrosis.

Treatment/Procedures

Diagnosis and evaluation of the activity of the disease by genetic testing, pulmonary function testing (breathing tests), bronchoalveolar lavage (lung washings) or possible open lung biopsy.

Contact

Joel Moss, M.D., Ph.D. 301-496-3632
National Heart, Lung, and Blood Institute

Lymphangioliomyomatosis (LAM)

Eligibility Requirements

Patients with known or suspected diagnosis of lymphangioliomyomatosis.

Treatment/Procedures

Diagnosis and evaluation of the activity of the disease by genetic testing, pulmonary function testing (breathing tests), bronchoalveolar lavage (lung washings) or possible open lung biopsy.

Contact

Joel Moss, M.D., Ph.D. 301-496-3632
National Heart, Lung, and Blood Institute

Sarcoidosis

Eligibility Requirements

Patients with known or suspected pulmonary sarcoidosis.

Treatment/Procedures

Diagnosis and evaluation of the activity of the disease by genetic testing, pulmonary function testing (breathing tests), bronchoalveolar lavage (lung washings) or possible open lung biopsy.

Contact

Joel Moss, M.D., Ph.D. 301-496-3632
National Heart, Lung, and Blood Institute

Reproductive Endocrine Disorders

Climacteric Perimenopause-related Dysphoria/Depression

Eligibility Requirements

Women in perimenopause/menopause and men ages 45 and older who are experiencing depressive symptoms. Must be in good physical health and medication free.

Treatment/Procedures

Hormonal evaluation; treatment.

Contact

Linda Simpson-St. Clair, R.N. 301-496-9576
National Institute of Mental Health

Depression-Postpartum

Eligibility Requirements

Women 18 to 40 years old with a history of postpartum depression but currently not depressed. Patients must have regular menstrual cycles and be medication free (including birth control pills).

Treatment/Procedures

Hormonal evaluation.

Contact

Linda Simpson-St. Clair, R.N. 301-496-9576
National Institute of Mental Health

Male Pseudohermaphroditism-5-alpha Reductase (Type 2) Deficiency

Eligibility Requirements

Adult males suspected of having male pseudohermaphroditism due to 5-alpha reductase deficiency based on clinical findings and a testosterone/DHT ratio greater than 16.

Treatment/Procedures

Administration of topical dihydrotestosterone cream for 6 months. Evaluation of penis and prostate size, body composition, bone density and turnover, hormonal profiles, and psychological responses.

Contact

Frank Czerwiec, M.D., Ph.D. or Michael Collins, M.D. 301-496-4686
National Institute of Child Health and Human Development

Premenstrual Syndrome

Eligibility Requirements

Women, 18 to 45 years old, experiencing mood changes in relationship to the menstrual cycle. Patients must have regular menstrual cycles and be medication free (including birth control pills).

Treatment/Procedures

Hormonal evaluation; treatment.

Contact

Linda Simpson-St. Clair, R.N. 301-496-9576
National Institute of Mental Health

Syndromic Diseases

Autoimmune Lymphoproliferative Syndrome (ALPS)

See *Immunologic Diseases*.

Chronic Fatigue Syndrome (CFS)

Eligibility Requirements

Individuals who are 18 to 50 years old; have chronic fatigue syndrome diagnosed by a physician, nurse practitioner or physician's assistant; are not taking certain medications including most antidepressants; do not have other chronic medical illnesses inclusive of but not restricted to hypertension, diabetes, heart disease, glaucoma, liver or kidney disease, or any significant medical or psychiatric illness requiring daily medication; must be able to travel to Baltimore, MD for the first tilt test. Only patients with a positive tilt test will be enrolled in the study.

Treatment/Procedures

A randomized, placebo-controlled trial is being conducted to determine whether patients with chronic fatigue syndrome who have neurally mediated hypotension diagnosed by a tilt table test will show improvement in their overall sense of wellness when treated with fludrocortisone.

Contact

Brenda Cuccherini, Ph.D., C.A.N.P. 1-800-772-5464 x659

Patricia Hohman, R.N. 1-800-772-5464 x610

National Institute of Allergy and Infectious Diseases

Chronic Fatigue Syndrome (CFS)

Eligibility Requirements

Individuals, 18 to 55 years of age, who meet the 1994 CDC and Prevention definition for CFS and as such, do not have other chronic medical diseases to which their symptoms can be attributed; are not dependent on drugs or alcohol; do not have contraindications for withholding all medications, with the exception of tylenol, immediately prior to and during study participation; are not pregnant or at high risk of acquiring infection with the AIDS virus; are able to travel to the NIH Clinical Center to participate in studies requiring a 1- to 2-week inpatient evaluation.

Treatment/Procedures

No treatment. Participation in studies designed to further understand features of the chronic fatigue syndrome, including provocative testing aimed towards the identification of biomarkers unique to CFS. No direct benefit to patient other than educational and contributing to general CFS knowledge components.

Contact

Janet K. Dale, R.N., M.Ph. 301-496-1699

Stephen E. Straus, M.D. 301-496-5221

National Institute of Allergy and Infectious Diseases

Lyme Disease, Chronic

See *Infectious Diseases*.

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Clinical Center Communications
NIH Publication No. 97-217
Revised 1997