

inflammatory response that results in fibrosis as seen in Crohn's disease. Preventing the inflammatory response of colitis by either modulating or blocking IL-13 and NKT cell activity continues to be an effective therapeutic approach in animal models of colitis with implications for the treatment of human ulcerative colitis and for the treatment of fibrosis associated with Crohn's disease.

Inventors: Warren Strober (NIAID), Ivan J. Fuss (NIAID), Peter Mannon (NIAID), Jan Preiss (NIAID), Raj Puri (FDA), Koji Kawakami (FDA), Stefan Fichtner-Feigl (NIAID), Atsushi Kitani (NIAID).

Related Publications:

1. F Heller, IJ Fuss, EW Nieuwenhuis, RS Blumberg, W Strober. Oxazolone colitis, a Th2 colitis model resembling ulcerative colitis, is mediated by IL-13-producing NK-T cells. *Immunity* 2002 Nov;17(5):629-628. [PubMed: 12433369].

2. IJ Fuss, F Heller, M Boirivant, F Leon, M Yoshida, S Fichtner-Feigl, Z Yang, M Exley, A Kitani, RS Blumberg, P Mannon, W Strober. Nonclassical CD1d-restricted NK T cells that produce IL-13 characterize an atypical Th2 response in ulcerative colitis. *J Clin Invest.* 2004 May 15;113(10):1490-1497. [PubMed: 15146247].

Patent Status: U.S. Patent Application No. 11/918,711 filed 14 Apr 2006 (HHS Reference No. E-003-2005/0-US-03) and related international filings.

Related Technologies:

- IL-13 modulators and inhibitors—U.S. Patent No. 7,666,411 issued 23 Feb 2010 (HHS Reference No. 131-2002/0-US-02), U.S. Patent Application No. 12/709,029 filed 19 Feb 2010 (HHS Reference No. E-131-2002/0-US-10), and related international filings.

- NF-kappa B decoy oligonucleotides—U.S. Patent Application No. 11/920,214 filed 09 Nov 2007 (HHS Reference No. E-108-2005/0-US-03).

Licensing Status: Available for licensing.

Licensing Contact: Betty B. Tong, Ph.D.; 301-594-6565; tongb@mail.nih.gov.

Dated: October 21, 2010.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2010-27177 Filed 10-26-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Guidelines for Use of Stored Specimens and Access to Ancillary Data and Proposed Cost Schedule: Stored Biologic Specimens and Ancillary Data From the Collaborative Perinatal Project (CPP)

ACTION: Notice and request for comments.

SUMMARY: The Division of Epidemiology, Statistics and Prevention Research (hereafter, Division) of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) maintains an extensive repository of datasets from completed studies, biospecimens, and ancillary data. The Division intends to make datasets and biospecimens more widely available to the research community for use by qualified researchers and to establish procedures for access consistent with the National Institutes of Health (NIH) Data Sharing Policy. The Division has established an internal committee, the Biospecimen Repository Access and Data Sharing Committee (BRADSC), to oversee the repository access and data sharing program. *The purpose of this notice is to request comments on this program and present the initial proposed cost schedule.* After full consideration of comments submitted in response to this notice, the BRADSC will finalize proposal guidelines and procedures, publish the cost schedule to the Division Web site, and begin to accept proposals for use of the stored biologic samples and for access to ancillary data that may not be available electronically. The first specimens and ancillary data that will be made available under this program are those from the national Collaborative Perinatal Project (CPP).

The CPP is a large, prospective cohort study, conducted by the National Institute of Neurological Diseases and Stroke (NINDS) of the National Institutes of Health (NIH), which recruited and enrolled 48,197 women who contributed 54,390 pregnancies that were prospectively followed from 1959-1966 at twelve academic medical centers across the United States. Custody for disposition of the CPP serum specimens was transferred to the Division from the NINDS in 1993 and for the microfiche archives in 1999. However, under the Federal Privacy Act of 1974 the samples and archive still belong to NINDS. Since 1992, the specimens have had limited public

availability through Division investigators. Going forward, the Biospecimen Repository Access and Data Sharing Committee (BRADSC) will oversee the repository access and data sharing program. Access to other Division resources will be announced on the Division Web site. The BRADSC reserves the right to amend the procedures and costs schedules as necessary to maintain the integrity of the program and to suit the conditions under which other specimens were collected. Announcements and current proposal guidelines will be available under the Research link at <http://despr.nichd.nih.gov>, and interested researchers should consult the Division Web site for resources available, the most recent guidelines for proposal submission and evaluation, and cost schedules. Procedures may vary depending on the age and nature of the samples and original institutional review board (IRB) approval, although the general outline of the procedures should remain the same. Cost schedules may vary depending on the nature and complexity of the request.

No funding is provided as part of this notice nor will any be available as part of the program either to support laboratory analyses or data management. Samples will only be provided to approved projects upon receipt of evidence of necessary IRB approval(s), funding and payment of repository costs and shipping. Approved projects that do not obtain funding will be canceled within one year of their approval date. A more complete description of this program follows. Comments or requests for clarification on all aspects of the program are welcome.

DATES:

- *Comment Receipt Date:* December 15, 2010.

- *Invitation to Submit Proposal:* Proposals can be submitted on an ongoing basis.

- *Scientific Review Dates:* Technical Panels for reviews will be assembled beginning on January 1, May 1, or September 1 of the calendar year so that proposals can be evaluated well in advance of Federal funding deadlines.

- *Anticipated Distribution of Samples:* Within one month of demonstrable proof of applicant IRB approval and receipt of payment to cover repository costs and shipping.

ADDRESSES: To send comments and to request information, *contact:* Dr. Mary L. Hediger, Division of Epidemiology, Statistics and Prevention Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6100 Executive Blvd,

Room 7B03, MSC 7510, Rockville, MD 20852, Phone: 301-435-6897, E-mail: hedigerm@exchange.nih.gov.

SUPPLEMENTARY INFORMATION:

The Collaborative Perinatal Project (CPP): The major stated aims of the CPP were to: (1) Determine the relationship between factors in the perinatal environment and the continuum of human reproductive failure, with particular reference to the central nervous system (CNS) for early (infancy and early childhood) and later (childhood) manifestations of deficits; (2) study the effect of the extra-uterine environment on fetal development (e.g., socio-economic factors, family structure); (3) determine the relationship of prematurity to factors in the perinatal environment and the continuum of human reproductive failure, with particular reference to the CNS; (4) study the clinico-pathological correlations in the continuum of human reproductive failure, with particular reference to the CNS; and (5) improve the classification, treatment and prevention of cerebral palsy. The Collaborative Perinatal Project (CPP) enrolled 48,197 women who contributed 54,390 pregnancies that were prospectively followed from 1959–1966 at twelve academic medical centers across the United States, including hospitals in Baltimore MD, Boston MA, Buffalo NY, Memphis TN, Minneapolis MN, New Orleans LA, New York NY (2 sites), Philadelphia PA, Providence RI, Portland OR, and Richmond VA. The women were recruited generally in the second trimester of pregnancy and followed through delivery. The children were followed periodically to seven or eight years of age. Data collection was concluded in 1974, and data were stored on computer tapes in “card image” format (80 columns/card).

A wide range of data was collected using standardized protocols and forms, including socio-demographic, obstetric, pediatric, infant neurological, and child psychological information. Electronic data files, forms, and documentation are available and accessible in the public domain. The CPP collected serum samples at recruitment, every eight weeks thereafter during pregnancy, and at the time of the delivery hospitalization. Cord blood was collected from approximately 60 percent of the infants, and some serum samples are available from women at six weeks postpartum. Residual serum and cord blood samples have been stored continuously in glass vials at –20 °C since collection, are inventoried, and are linkable to individual electronic

records by the original CPP identification number. A microfiche archive is also stored and available, compiled by identification number, and containing CPP completed forms and records with ancillary information, original medical notes, and comments.

In 1983, electronic data files, forms, and documentation were compiled from the original tapes and manuals, documented, and written to other media. The data and documentation are currently available and accessible in the public domain (e.g., <http://www.nber.org/cpp/docs/>). In addition to the files available electronically, the CPP collected serum samples at recruitment, subsequently every eight weeks during pregnancy, and at the time of the delivery hospitalization. Cord blood was collected from approximately 60 percent of the infants, and some serum samples are available from women at six weeks postpartum. Residual serum and cord blood samples have been stored continuously in glass vials at –20 °C since collection, are inventoried, and are linkable to individual electronic records by the original CPP identification number. A microfiche archive, compiled by identification number containing CPP completed forms and records with ancillary information, original medical notes, and comments, is also stored and available.

There are CPP serum samples from at least 53,515 pregnancies from 46,424 women available for research proposals using CPP samples. There are approximately 32,130 samples of cord blood.

Clinical Significance: Because the CPP samples were collected before controlling guidelines were available, participants did not consent to future use. Therefore, only research projects that propose laboratory results or findings in the ancillary data that do *not* have immediate clinical significance to an individual will be deemed acceptable for the CPP. Applicants should address this clearly in the research proposal.

Clinical significance for laboratory studies is defined by the following criteria:

The findings are valid and done by a CLIA-certified laboratory; and
The findings may have significant immediate implications for the subjects' health concerns; and
A course of action to ameliorate, or treat the concerns is readily available.

Clinical significance for ancillary findings is defined:

The findings may have significant immediate implications for the

subjects' or their family's health concerns; and

A course of action to ameliorate, or treat the concerns is readily available.

Proposals for Use of the Samples and Access to the Ancillary Data: All proposals for use of CPP samples and access to the ancillary data will be evaluated by an *ad hoc* Technical Panel for scientific merit. The BRADSC will generally rely on the investigators' approval of the proposal by their institutional review board (IRB) for use of the samples and access, although the BRADSC reserves the right in questionable cases to have the NICHD IRB review the proposal even if the investigators have already received approval by their IRB.

Evaluation Criteria: To determine if the biologic specimens (a limited resource) should be used in the proposed projects or if an applicant should be given access to the microfiche archives, an *ad hoc* Technical Panel, chosen and overseen by BRADSC and comprised of two content and one statistical reviewer, will evaluate the public health significance and scientific merit of each proposed research project. Applicants may be asked to suggest outside reviewers, but the final composition of the Technical Panel will be at the discretion of the BRADSC. Scientific merit will be judged as to the scientific, technical or medical significance of the research, the appropriateness and adequacy of the experimental approach, and the methodology proposed to reach the research goals. If the project involves biologic specimens, the Technical Panel will also consider the amount of sample requested and weigh the significance of the research against the amount of sample requested and that remaining. Investigators are encouraged to request the smallest amount of sample possible consistent with best scientific practices and the aims of their study. The proposal should outline how the results from the laboratory analysis or findings from the original forms will be used. The appropriateness of the CPP sample to address the goals of the proposal will be an important aspect of scientific merit. The Technical Panel will review the analysis plan and evaluate whether the proposal is an appropriate use of the CPP population and likely to be successful. The Technical Panel will also assure that the proposed project does not go beyond the specific stated goals of the proposal. Investigators are encouraged to review the CPP forms and documentation at: <http://despr.nichd.nih.gov> or <http://www.nber.org/cpp/docs/>. The Division Web site will also have posted

accessible copies of pertinent publications on the history of the CPP and scientific papers with notable findings.

Procedures for Proposals: All investigators (including NIH and NICHD investigators) must submit a proposal for use of CPP specimens. Proposals are limited to a maximum of ten (10) single-spaced typed pages, excluding figures and tables, using 12 cpi type density. The proposal should be comprehensive and tailored to the request and not simply be sections lifted from another Federal or foundation application. The cover of the proposal should include the name, address, and phone number and e-mail address of the Principal Investigator (PI) and the name of the institution where the laboratory analysis will be done if they are a component of the project. All proposals should be e-mailed to the address specified on the Web site. Proposals must include a cover page with the title of the proposal and the name, address, phone number and e-mail address of all investigators. The following criteria will be used for technical evaluation of proposals:

Proposals should include the following information:

(1) *Specific Aims:* List the broad objectives; describe concisely and realistically what the research is intended to accomplish, and state the specific hypotheses to be tested.

(2) *Background and Public Health Significance:* Describe the public health significance, scientific merit and practical utility of the assay or information. Briefly describe in one or two pages the background of the proposal, identifying how the project may also relate to previous (published) analyses of the CPP and gaps in knowledge that the project is intended to fill. State concisely the importance of the research in terms of the broad, long-term objectives and public health relevance including a discussion of how the results will affect public health policy or further scientific knowledge. The proposer should convey how the results will be used and the relationship of the results to the data already collected in the CPP. The applicant should include an analysis plan. Applicants are encouraged strongly to have a statistical consultant or someone knowledgeable about statistics be part of the investigative team or nominally review the plan before submission. The analyses ought to be consistent broadly with the CPP aims and the health status variables.

(3) *Research Design and Methods:* Describe the research design and the procedures to be used. Data and/or biospecimen requests should specify the

exact variable(s) or sample name(s) as provided in the CPP documentation or give an expectation of findings in notes or other forms in the microfiche archive. If there is a laboratory component, a detailed description of laboratory methods including validity and reliability must be included with references. Because the samples were collected over forty years ago, applicants should consider how aging might have affected the samples. If no data are available on how aging might have affected the samples, a limited number of samples of the same historical age are available for pilot studies. Even if the proposal is meritorious, the BRADSC may expect, upon advice of the Technical Panel, that a pilot be completed before all specimens requested are released to the investigators.

The volume of specimen and number of samples requested must be specified. Adequate methods for handling and storage of samples must also be addressed. The laboratory must demonstrate expertise in the proposed laboratory test including the capability for handling the workload requested in the proposal. The proposal should also include a justification for determination of study sample size or a power calculation. If the researcher is requesting a regional or targeted sub-sample of specimens, a detailed description and justification must be given. The study design and analysis plan in the proposal will be evaluated to determine whether the project is feasible and can be performed using the CPP.

(4) *Clinical Significance or Results:* Since individual results cannot be provided, the clinical significance of the proposed laboratory test should be addressed. The proposal should include a discussion of the potential clinical significance of the results and whether there is definitive evidence that results of the test would provide grounds for medical intervention even given that many years have passed since the examination of the participant and collection of the sample. Any test with results that should be reported immediately to a participant is not appropriate for testing on the stored samples.

(5) *Qualifications:* Provide a brief description of the Principal Investigator and other investigators' expertise in the proposed area, including publications in this area within the last three years. A representative sample of earlier publications may be listed as long as this section does not exceed two pages.

(6) *Period of performance:* Specify the project period. Substantial progress

must be made in the first year, and the project should be completed in two years. If additional time is needed for the research project a detailed justification with a timeline should be included. The investigators should address their ability to comply with this timeline or request and justify additional time for the project. Return of the specimens will be requested if progress is not made in the project at the end of the second year. Refund of payment for the specimens will not be returned in this situation. At the end of the project period, any unused samples must be returned to the Division Repository or discarded, according to the wishes of the BRADSC. Within six months to one year of the end of the project period, and consistent with NIH Data Sharing guidelines, the investigators will submit to the Division for access by the wider research community a complete and clean copy of the new data obtained, whether from laboratory analyses or the microfiche archives, coded and linkable to the main CPP database through the study ID, documentation, and a letter from the PI certifying the data.

(7) *Funding:* Include the source and status of the funding to perform the requested laboratory analysis should be included. Investigators will be responsible for the cost of processing and shipping the samples. The basis for the cost structure is in the last section of this notice. Reimbursement for the samples will be collected before the samples are released.

Submission of Proposals: Proposals can be submitted in MS Word or pdf format by e-mail to: hedigerm@exchange.nih.gov.

Summary of Evaluation Criteria: (1) Relevance of the study question to current research; (2) adequacy of the study design to address the question; (3) feasibility and appropriateness of the CPP for conducting the study; (4) if there is a laboratory component, appropriateness of the assay, including evidence that the analyte is stable under prolonged storage at -20°C ; and (5) experience of the investigators in conducting similar studies, including knowledge of the CPP.

Approved Proposals: Approved projects will be provided specimens upon receipt of a check to cover the cost of accessing, preparing, and shipping the specimens. Approved projects requesting access to the microfiche archives will be granted access once arrangements have been made with the Division. Approved and funded projects will be posted by title and abstract on the Division Web site once specimens have been shipped. *Note* that

biospecimens will be distributed blinded, that is, with an identifier that will only be linked to the study identification number upon completion of laboratory analyses, unless arrangements have been made for interim analyses beforehand.

Progress Reports: Brief progress reports must be submitted annually to judge progress.

Disposition of Results and Samples: No samples provided can be used for any purpose other than those specifically requested in the proposal and approved by the Technical Panel. No sample can be shared with others, including other investigators, unless specified in the proposal and so approved. Any unused samples must be either discarded or returned to the Division Repository, according to the wishes of the BRADSC upon completion of the approved project.

Proposed Cost Schedule for Providing CPP Specimens: A nominal processing fee of approximately \$8.00–\$16.00 per sample, plus express shipping costs is anticipated for each sample requested and received. Costs will be fully estimated at the time of proposal acceptance and will take into consideration time and materials for the collection, storage and processing of the specimens by the Division Repository along with the preparation of the accompanying data files. The material costs are for the recurring laboratory costs to dispense and prepare the samples during collection and the computer software needed for the preparation of the data files. Because size of the shipments and distance to laboratories may vary, shipping costs will be estimated at the time of proposal acceptance. Cost reimbursement structures negotiated and accepted as part of a final proposal acceptance will be honored for one year from the date of proposal acceptance.

Proposed Cost for Accessing CPP Microfiche Archives: There is no direct cost for accessing the CPP microfiche archives, although arrangements will have to be made for access to the building and is dependent upon the space available to accommodate a researcher.

As additional specimens and resources from Division projects are made available for public use, announcements will be made on the Division Web site without further announcement in the **Federal Register**. As a reminder, the BRADSC and Division reserve the right to amend the proposal guidelines and cost schedule as needed and in keeping with the nature and complexity of the applicants' request.

Dated: October 20, 2010.

Germaine M. Buck Louis,

Director and Senior Investigator, Division of Epidemiology, Statistics, and Prevention Research, Eunice Kennedy Shriver National Institute of Child Health and Human Development.

[FR Doc. 2010–27183 Filed 10–26–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; NRSA Institutional Research Training (T32).

Date: November 17, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Melrose Hotel, 2430 Pennsylvania Ave., NW., Washington, DC 20037.

Contact Person: Aileen Schulte, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd, Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–1225, aschulte@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Novel NeuroAIDS Therapeutics.

Date: November 22, 2010.

Time: 12 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: David W Miller, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–9734, millerda@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development

Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: October 20, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–27186 Filed 10–26–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Skeletal Muscle and Exercise Physiology.

Date: November 10–11, 2010.

Time: 9 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting)

Contact Person: Richard Ingraham, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7814, Bethesda, MD 20892, 301–496–8551, ingrahamrh@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, RFA Panel: Developmental Pharmacology.

Date: December 6–7, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting)

Contact Person: Janet M Larkin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of