

(CHD) and stroke in people age 65 years and older. The primary objectives include quantifying association of risk factors with subclinical disease; characterize the natural history of CHD and stroke; and identify factors associated with clinical course. The findings will provide important information on cardiovascular disease in an older U.S. population and lead to

early treatment of risk factors associated with disease and identification of factors which may be important in disease prevention. *Frequency of Response:* Twice a year (participants) or once per cardiovascular disease event (proxies and physicians); *Affected Public:* Individuals. *Type of Respondents:* Individuals recruited for CHS and their selected proxies and

physicians. The annual reporting burden is as follows: *Estimated Number of Respondents:* 4,606; *Estimated Number of Responses Per Respondent:* 4.55; and *Estimated Total Annual Burden Hours Requested:* 1,719. There are no capital, operating, or maintenance costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent*	Average burden hours per response	Estimated Total annual burden hours requested
Participants .....	3,580	5.6	0.25	1,665
Physicians .....	606	1.0	0.10	20
Participants proxies .....	420	1.0	0.25	35
Total .....	4,606	4.55	0.246	1,719

\*Total over 3-year period.

**Request for Comments:** Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility, (2) the accuracy of the agency's estimated of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**Direct Comments to OMB:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Diane Build, National Institutes of Health, Division of Epidemiology and Clinical Applications, Epidemiology and Biometry Program, NHLBI, II Rockledge Centre, 6701 Rockledge Drive, MSC # 7934, Bethesda, MD, 20892-7934, or call non-toll-free number (303) 435-0707, or e-mail your

request, including your address to: bild@nih.gov.

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received on or before April 11, 2001.

Dated: March 1, 2001.

**Peter J. Savage,**

*Acting Director, Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute.*

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**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; Comment Request; Survey of IRB Chairs Concerning the Implementation of Pediatric Research Regulations

**SUMMARY:** Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Clinical Center, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on October 17, 2000, page 61341 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1,

1995, unless it displays a currently valid OMB control number.

**Proposed Collection: Title:** Survey of IRB Chairs Concerning the Implementation of Pediatric Research Regulations. **Type of information Collection Request:** New. **Need for Use of Information Collection:** In order to assess the protection of children who are enrolled in clinical research, it is important to determine how Institutional Review Boards (IRBs) reviewing such research interpret and implement the Federal Regulations for research with children set forth in 45 CFR 45 subpart D. This study aims to gather this information through telephone interviews with chairpersons of IRBs that review clinical research with children. In addition, we will solicit background information on each IRB from the IRB chair. In particular, the survey aims to assess how IRBs assess risk/benefit levels of research with children, when IRBs permit children's assent to be waived, what information IRBs require children to be presented during the assent process, and which children are excluded from participation in riskier research. In addition, the survey will attempt to determine how the recent NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects has affected IRB review. **Frequency of Response:** Once. **Affected Public:** Individuals. **Type of Respondents:** IRB chairpersons. The annual reporting burden follows in the table below. The annualized cost to respondents is estimated at: \$10,000. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

## RESPONDENT AND BURDEN ESTIMATE INFORMATION

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
IRB chairs .....	400	1	0.5	200
Total .....	400	.....	.....	200

**Request for Comments:** Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**Direct Comments to OMB:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dave Wendler, Ph.D., Head, Unit on Vulnerable Populations, Department of Clinical Bioethics, NIH, Building 10, Room 1C118, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 435-8726 or fax or e-mail your request, including your address, to: Facsimile number (301) 496-0760 and email address [DWendler@cc.nih.gov](mailto:DWendler@cc.nih.gov).

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received on or before April 11, 2001.

Dated: March 2, 2001.

**David K. Henderson,**  
Deputy Director, Warren G. Magnuson  
Clinical Center, National Institutes of Health.  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute (NCI) Collaborative Development of Methods for Selective T Cell Depletion To Improve Bone Marrow Transplantation Procedures

Opportunities for Collaborative Research and Development Agreements are available for collaboration with the Biological Resources Branch (BRB), Developmental Therapeutics Program (DTP), Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI) to develop methods that could be applicable, in the setting of clinical bone marrow transplants, to deplete selected populations of T cells prior to the infusion of donor cells into the recipient. Selective T cell population depletion has been suggested as a possible approach to the goal of reducing the incidence of Graft versus Host Disease (GVHD) associated with bone marrow transplants, with the goal of also retaining clinical antitumor efficacy.

**AGENCY:** National Cancer Institute, National Institutes of Health, PHS, DHHS.

**ACTION:** Notice of opportunities for cooperative research and development agreements (CRADAs).

**SUMMARY:** Pursuant to the Federal Technology Transfer Act of 1986 (15 U.S.C. 3710a; and Executive Order 12591 of April 10, 1987) as amended, the National Cancer Institute (NCI) of the National Institutes of Health (NIH) of the Public Health Service (PHS) of the Department of Health and Human Services (DHHS) seeks one or more Cooperative Research and Development Agreements (CRADAs) with pharmaceutical or medical device companies to discover and develop potential new methods of *ex vivo* depletion of selected populations of donor T cells with the goal of reducing Graft versus Host Disease (GVHD) in the transplant recipient, while still retaining antitumor efficacy. Each CRADA would have an expected duration of one (1) to

five (5) years. The goals of the CRADA include the rapid publication of research results and timely commercialization of products, and methods of treatment or prevention that may result from research. The CRADA collaborator will have an option to negotiate an exclusive or non-exclusive license to subject inventions arising under the CRADA and which are a subject of the CRADA Research Plan.

Proposals and questions about this CRADA opportunity may be addressed to Donna L. Bialozor, Technology Development Specialist, Technology Development & Commercialization Branch, National Cancer Institute-Frederick, 1003 West Seventh Street, Fairview Center, Room 502, Frederick, MD 21701 (Phone 301-846-5465; Fax: 301-846-6820; E-mail: [bialozod@mail.nih.gov](mailto:bialozod@mail.nih.gov)).

Scientific inquiries should be submitted to Dr. Stephen Creekmore, Chief, Biological Resources Branch (BRB), Developmental Therapeutics Program (DTP), National Cancer Institute-Frederick Research & Development Center, Building 1052, Room 251, NCI-Frederick, P.O. Box B, Frederick, MD 21702-1201 (Phone: 301-846-1100; Fax: 301-846-5429; E-mail: [creekmor@mail.ncicrf.gov](mailto:creekmor@mail.ncicrf.gov)).

Inquiries regarding CRADA proposals and scientific matters may be forwarded at any time. Confidential, preliminary CRADA proposals, preferably five pages or less, must be submitted to the NCI within 90 days from the date of this publication. Guidelines for preparing final CRADA proposals will be submitted shortly thereafter to all respondents with whom initial confidential discussions will have established sufficient mutual interest. CRADA proposals submitted at a later date may be considered if a suitable CRADA collaborator has not been selected.

### Technology Available

The Biological Resources Branch (BRB) of the Developmental Therapeutics Program (DTP) is an NCI extramural research activity with a mission to evaluate and support development of innovative