

## APPENDIX.—DERIVATION OF "MARKET BASKET" INDEX FOR SNF ROUTINE SERVICE COSTS—Continued

Category of costs	Relative <sup>1</sup> importance 1993	Price variable used <sup>2</sup>
Employee Benefits .....	7.8	Supplements to wages and salaries per worker in nonagricultural establishments. For supplements to wages. Source: U.S. Dept. of Commerce, Bureau of Economic Analysis, <i>Survey of Current Business</i> . Table 1.11. For total employment. Source: U.S. Dept. of Labor, Bureau of Labor Statistics, <i>Employment and Earnings</i> (monthly). Table B-4.
Food .....	7.6	Processed foods and feeds component of producer price index. Source: U.S. Dept. of Labor, Bureau of Labor Statistics, <i>Monthly Labor Review</i> , Table 23. Food and beverage component of Consumer Price Index, all urban. Source: U.S. Dept. of Labor, Bureau of Labor Statistics, <i>Monthly Labor Review</i> , Table 22.
Other business services .....	5.1	Services component of Consumer Price Index, all urban. Source: U.S. Dept. of Labor, Bureau of Labor Statistics, <i>Monthly Labor Review</i> , Table 23.
Fuel and other utilities .....	4.0	A. Implicit price deflator-consumption of fuel oil and coal (derived from fuel oil component of Consumer Price Index). Source: U.S. Dept. of Commerce, Bureau of Economic Analysis, <i>Survey of Current Business</i> (monthly), Table 7.11. B. Implicit price deflator-consumer of electricity (derived from electricity component of Consumer Price Index). Source: U.S. Dept. of Commerce, Bureau of Economic Analysis. C. Implicit price deflator for natural gas (derived from utility (piped) gas component of Consumer Price Index). Source: Same as electricity above. D. Water and sewage maintenance component of the Consumer Price Index. Source: U.S. Dept. of Labor, Bureau of Labor Statistics, <i>Monthly Labor Review</i> , Table 23.
Supplies .....	3.1	All Item Consumer Price Index, all urban. Source: U.S. Dept. of Labor, Bureau of Labor Statistics, <i>Monthly Labor Review</i> , Table 23.
Drugs .....	2.2	Pharmaceutical preparations, ethical component of producer price index. Source: U.S. Dept. of Labor, Bureau of Labor Statistics, <i>Producer Prices and Price Indexes</i> (monthly), Table 6.
Health services .....	1.6	Physician services component of Consumer Price Index for all urban consumers. Source: U.S. Dept. of Labor, Bureau of Labor Statistics, <i>Monthly Labor Review</i> , Table 23.
Miscellaneous .....	4.6	All Item Consumer Price Index, all urban. Source: U.S. Dept. of Labor, Bureau of Labor Statistics, <i>Monthly Labor Review</i> , Table 23.

<sup>1</sup> The basic weights for all major categories of skilled nursing home costs were obtained from the DHEW-National Center for Health Statistics (NCHS) National Nursing Home Surveys (NNHS) for 1972 and 1976 for home certified for participation in the Medicare program. See *Nursing Home Costs 1972, United States: National Nursing Home Survey, August 1973–April 1974, DHEW, NCHS: National Nursing Home Survey: 1977 Summary for the United States, Vital and Health Statistics, Series 13, Number 43*.

A Laspeyres price index was constructed using 1977 weights and price variables indicated in this table. In calendar year 1977 each "price" variable has an index of 100.0. The relative routine service cost weights change each period in accordance with price changes for each price variable. Cost categories with relatively higher "price" increases get relatively higher cost weights and vice versa.

<sup>2</sup> Forecasted by DRI/McGraw Hill, Health Care Costs, First Quarter, 1992, 1750 K St., NW, Washington D.C. 20006.

Authority: Secs. 1102, 1814(b), 1861(v)(1), 1866(a), 1871, and 1888 of the Social Security Act (42 U.S.C. 1302, 1395f(b), 1395x(v)(1), 1395cc(a), 1395hh, and 1395yy); sec. 13503(b) and (c) of Pub. L. 103–66 (42 U.S.C. 1395x(v)(1)(B) and 1395yy (note)) and 42 CFR 413.1, 413.24, and 413.300 through 413.321).  
(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

Dated: July 1, 1996.

Bruce C. Vladeck,  
*Administrator, Health Care Financing Administration.*

Dated: August 2, 1996.

Donna E. Shalala,  
*Secretary.*  
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## National Institutes of Health

### National Cancer Institute: Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Scientific and Commercial Development of Fusion Proteins That Include Antibody and Non-Antibody Portions

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

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (DHHS) seeks one or more companies that can collaboratively pursue the pre-clinical and clinical development of Fusion Proteins That Include Antibody and Non-Antibody Portions. The following disease states are of interest: neoplasia, arteriosclerosis, tumor vascularization, fibrotic diseases, psoriasis and wound healing. The National Cancer Institute, Laboratory of Cellular and Molecular Biology has developed an assay system to identify receptor agonists and antagonists using fusion protein

technology. The selected sponsor will be awarded a CRADA with the National Cancer Institute for the co-development of agents identified using the fusion protein technology.

**ADDRESS:** Questions about this opportunity may be addressed to Jeremy A. Cubert, M.S., J.D., Office of Technology Development, NCI, 6120 Executive Blvd. MSC 7182, Bethesda, MD 20892–7182, Phone: (301) 496–0477, Facsimile: (301) 402–2117, from whom further information may be obtained.

**DATE:** In view of the important priority of developing new agents for the treatment or prevention of cancer, interested parties should notify this office in writing no later than October 18, 1996. Respondents will then be provided an additional 30 days for the filing of formal proposals.

#### SUPPLEMENTARY INFORMATION:

"Cooperative Research and Development Agreement" or "CRADA" means the anticipated joint agreement to be entered into by NCI pursuant to the Federal Technology Transfer Act of

1986 and amendments (including 104 P.L. 133) and Executive Order 12591 of October 10, 1987 to collaborate on the specific research project described below.

The Government is seeking one or more companies which, in accordance with the requirements of the regulations governing the transfer of agents in which the Government has taken an active role in developing (37 CFR 404.8), can further develop the identified compounds and related diagnostic methods through Federal Food and Drug Administration approval and to a commercially available status to meet the needs of the public and with the best terms for the Government. The government has applied for domestic and foreign patent applications directed to Fusion Proteins That Include Antibody and Non-Antibody Portions.

The Fusion Proteins comprise an IgG sequence covalently joined at the IgG hinge and Fc domain to a non-antibody effector domain such as a ligand, toxin, or receptor. The effector domain or IgG non-antibody portion may be linked to a heterologous signal peptide to facilitate secretion. The resulting fusion protein exhibits the effector properties of both the antibody and non-antibody portions. Applications of this technology include development of diagnostic methods to monitor binding and expression of a protein of interest *in vitro*, *in vivo* and *in situ* (i.e. immunohistochemistry). In addition, the technology can be used to identify agonists and antagonists that modulate the binding of an effector molecule to its target. Fusion proteins may also be employed as a therapeutic to deliver radiation, a cytotoxic agent or a drug directly to a target cell.

The LCMB, Division of Basic Sciences, NCI is interested in establishing a CRADA with one or more companies to assist in the development of diagnostic, screening and therapeutic applications of the technology. The Government will provide all available expertise and information to date and will jointly pursue pre-clinical and clinical studies as required, giving the company full access to existing data and data developed pursuant to the CRADA. The successful company will provide the necessary scientific, financial and organizational support to establish clinical efficacy and possible commercial status of subject compounds and/or diagnostic and therapeutic applications.

The expected duration of the CRADA will be two (2) to five (5) years.

The role of the National Cancer Institute, includes the following:

1. Construction of fusion proteins comprising a molecule of interest covalently joined to an IgG hinge and Fc antibody regions.
2. Expression and harvesting of the resulting fusion protein from conditioned medium of a suitable transfectant such as NIH 3T3 cells.
3. Develop a screen of ligand-HFc on receptor or receptor-HFc on ligand to identify putative agonists and antagonists.
4. Conduct *in vitro* studies to identify putative agonists and/or antagonists by screening libraries of compounds.
5. Conduct *in vitro* and *in vivo* studies to characterize the properties of putative agonists and/or antagonists.
6. Evaluation of test results.
7. Preparation of manuscripts for publication.

Relevant Government intellectual property rights are available for licensing through the Office of Technology Transfer, National Institutes of Health.

**FOR FURTHER INFORMATION CONTACT**  
Susan Rucker, J.D., NIH Office of Technology Transfer, 6011 Executive Blvd, Suite 325, Rockville, MD 20852, Phone: (301) 496-7056 (ext. 245); Facsimile: (301) 402-0220.

The role of the collaborator company, includes the following

- For agonist/antagonist screening:
1. Provide growth factor or receptor cDNA clones for fusion protein construction if not available in NCI/LCMB clone bank
  2. Scale-up production of fusion proteins constructed by NCI if required
  3. Conduct *in vitro* studies to identify putative antagonists/agonists by screening libraries of compounds
  4. Conduct *in vitro* and *in vivo* studies to characterize the properties of putative antagonists/agonists
  5. Conduct clinical studies of best candidates
- For ligand-mediated histochemical experiments:
1. Test conditioned medium for suitability in histochemical experiments
  2. Screen tumor samples or biopsies for reactivity
  3. Conduct clinical studies of diagnostic test

Criteria for choosing the company include its demonstrated experience and commitment to the following:

1. Scientific expertise in and demonstrated commitment to the treatment of neoplasia, arteriosclerosis, fibrotic diseases and related disorders.
2. Scientific expertise in and demonstrated commitment to the development of drug delivery systems.

3. Experience in preclinical and clinical drug development.

4. Experience and ability to produce, package, market and distribute pharmaceutical products.

5. Experience in the monitoring, evaluation and interpretation of the data from investigational agent clinical studies under an IND.

6. A willingness to cooperate with the NCI in the collection, evaluation, publication and maintaining of data from pre-clinical studies and clinical trials regarding the subject compounds.

7. Provide defined financial and personnel support for the CRADA to be mutually agreed upon.

8. An agreement to be bound by the DHHS rules involving human and animal subjects.

9. The aggressiveness of the development plan, including the appropriateness of milestones and deadlines for preclinical and clinical development.

10. Provisions for equitable distribution of patent rights to any CRADA inventions. Generally the rights of ownership are retained by the organization which is the employer of the inventor, with (1) an irrevocable, nonexclusive, royalty-free license to the Government and (2) an option for the collaborator to elect an exclusive or nonexclusive license to Government owned rights under terms that comply with the appropriate licensing statutes and regulations.

Dated: August 14, 1996.

Thomas D. Mays,  
*Director, Office of Technology Development, OD, NCI.*

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### **National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting**

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 United States Code Appendix 2), notice is hereby given of the following meeting:

*Name of Committee:* National Institute on Deafness and Other Communication Disorders Special Emphasis Panel.

*Date:* September 10-11, 1996.

*Time:* September 10-8 am to 5 pm; September 11-8 am to adjournment.

*Place:* Holiday Inn, Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

*Contact Person:* Mary Nekola, Ph.D., Scientific Review Administrator, NIDCD/DEA/SRB, EPS Room 400C, 6120 Executive Boulevard, MSC 7180, Bethesda, MD 20892-7180, 301-496-8683.

*Purpose/Agenda:* To review and evaluate grant applications. The meeting will be