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To obtain copies of the supporting statement for the proposed paperwork collections referenced above, or any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: April 30, 1998.
John P. Burke III,
HCFA Reports Clearance Officer, Division of HCFA Enterprise Standards, Health Care Financing Administration.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Announcement of Office of Management and Budget (OMB) Control Numbers for Agency Information Collections Approved Under the Paperwork Reduction Act of 1995

AGENCY: Health Care Financing Administration, HHS.

This notice announces and displays OMB control numbers for Health Care Financing Administration (HCFA) information collections that have been approved by OMB.

Under OMB's regulations implementing the Paperwork Reduction Act (PRA), 44 U.S.C. 3501, each agency that proposes to collect information

must submit its proposal for OMB review and approval in accordance with 5 CFR Part 1320. Once OMB has approved an agency's proposed collection of information and issues a control number, the agency must display the control number.

OMB regulations provide for alternative methods of displaying OMB control numbers. In the case of collections of information published in regulations, display is to be "provided in a manner that is reasonably calculated to inform the public." To meet this requirement an agency may display such information in the **Federal Register** by publishing such information in the preamble or the regulatory text, or in a technical amendment to the regulation, or in a separate notice announcing OMB approval of the collection of information.

To comply with this requirement HCFA has chosen to publish this notice announcing OMB approval of the collections of information published in regulations. As stated above, this notice announces and displays the assigned OMB control numbers for HCFA's information collections that have been approved by OMB.

	OMB control Nos.
42 CFR :	
403.210	0938-0640.
405.262	0938-0267.
405.374	0938-0270.
405.427	0938-0155.
405.711	0938-0045.
405.807	0938-0033.
405.821	0938-0034.
405.1632	0938-0454.
405.1701-1726	0938-0273.
405.2100-2171	0938-0386.
405.2110, 405.2112	0938-0657 and 0658.
405.2133	0938-0046 and 0447 and 0448.
405.2135-2171	0938-0360.
405.2401	0938-0685.
406.13	0938-0080.
406.15	0938-0501.
406.28, 407.27	0938-0025.
407.10, 407.11	0938-0245.
407.18	0938-0679.
407.40	0938-0035.
408.6	0938-0041.
409.40-50	0938-0357.
410.1	0938-0679.
410.36	0938-0357.
410.38	0938-0534.
410.40	0938-0042 and 0685.
410.69	0938-0685.
410.170	0938-0357.
411.4-15	0938-0357.
411.15	0938-0224 and 0357.
411.20-411.206	0938-0565.
411.372, 411.373, 411.378	0938-0714.
411.404, 411.406	0938-0465.
411.408	0938-0566.
412.20-32	0938-0358.
412.40-62	0938-0359.

	OMB control Nos.
412.44, 412.46	0938-0445.
412.92	0938-0477.
412.105	0938-0456.
412.106	0938-0691.
412.116	0938-0269.
412.256	0938-0573.
413.13	0938-0463.
413.16	0938-0583.
413.17, 413.20	0938-0202.
413.20, 413.24	0938-0022 and 0037 and 0050 and 0102 and 0107 and 0301 and 0463 and 0511.
413.56	0938-0463.
413.64	0938-0269.
413.157	0938-0463.
413.170	0938-0296.
413.198, 413.200	0938-0236.
414.40	0938-0008.
414.330	0938-0372.
414.451, 414.452, 414.456, 414.460	0938-0685.
416.43	0938-0506.
416.47	0938-0266 and 0506.
417.1-106	0938-0469.
417.124	0938-0472.
417.126	0938-0701.
417.143	0938-0470.
417.162	0938-0469.
417.408	0938-0470.
417.436	0938-0610.
417.470	0938-0701.
417.479, 417.500	0938-0700.
417.801	0938-0610.
418.22, 418.24, 418.28, 418.30, 418.56, 418.58, 418.70, 418.74, 418.80, 418.83, 418.96, 418.100	0938-0302.
420.200-206	0938-0086.
421.100	0938-0357.
422.430	0938-0390.
424.5	0938-0534.
424.20	0938-0454.
424.22	0938-0357 and 0489.
424.32	0938-0008.
424.57	0938-0685.
424.73	0938-0685.
424.123	0938-0484.
424.124	0938-0042.
430.10-20	0938-0193.
430.12	0938-0610 and 0673.
431.20	0938-0610.
431.1-431.865	0938-0062.
431.17	0938-0467.
431.110	0938-0390.
431.107	0938-0610.
431.306	0938-0502.
431.630	0938-0445.
431.800	0938-0094 and 0300.
431.802-822	0938-0246.
431.814	0938-0146 and 0147.
431.820	0938-0144.
431.865	0938-0094 and 0246.
431.940-431.965	0938-0467.
433.68, 433.74	0938-0618.
433.110-131	0938-0487.
433.110, 433.112-433.114, 433.116, 433.117, 433.119, 433.121, 433.122, 433.127, 433.130, 433.131	0938-0247.
433.138	0938-0502.
433.139	0938-0502.
434.27	0938-0572.
434.28	0938-0610.
434.44, 434.67, 434.70	0938-0700.
435.1-435.1011	0938-0062.
435.217, 435.726, 435.735	0938-0449.
435.940-965	0938-0467.
440.1-270	0938-0062.
440.10	0938-0449.
440.30	0938-0685.

	OMB control Nos.
440.167	0938-0193.
440.180	0938-0272.
441.16	0938-0713.
441.250-300	0938-0481.
441.300-305	0938-0272.
441.302	0938-0449.
442.1-119	0938-0062 and 0379.
442.10-119	0938-0355.
442.30	0938-0678.
447.31	0938-0287.
447.53	0938-0429.
447.253	0938-0523.
447.272	0938-0618.
447.280	0938-0624.
447.299	0938-0618.
447.500-542	0938-0676.
447.550	0938-0676.
455.100-106	0938-0086.
456.650-657	0938-0061.
456.654	0938-0445.
456.700, 456.705, 456.709, 456.711, 456.712	0938-0659.
466.71, 466.73, 466.74, 466.78, 466.80, 466.94	0938-0445.
473.18, 473.34, 473.36, 473.42	0938-0443.
476.104, 476.105, 476.116, 476.134	0938-0426.
482.1-66.	0938-0380.
482.2-57	0938-0382.
482.12, 482.22	0938-0328.
482.27	0938-0328 and 0698.
482.41	0938-0242.
482.30, 482.41, 482.43, 482.53, 482.56, 482.57, 482.60-62	0938-0328 and 0378.
482.66	0938-0328 and 0624.
483.10	0938-0610.
483.70	0938-0242.
483.400-480	0938-0062 and 0678.
483.470	0938-0242.
484.1-52	0938-0365.
484.10	0938-0610.
484.18	0938-0357.
484.48	0938-0519.
484.52	0938-0687.
485.56, 485.58, 485.60, 485.64, 485.66	0938-0267.
485.701-729	0938-0273 and 0065.
485.709, 485.711, 485.717, 485.719, 485.721, 487.723, 485.725, 485.727, 485.729	0938-0336.
486.100-110	0938-0338.
486.150-163	0938-0258 and 0071.
486.155, 486.161, 486.163	0938-0336.
486.301-325.	0938-0391, 0512 and 0688.
488.1-28	0938-0355.
488.4	0938-0690.
488.18	0938-0667.
488.26	0938-0379.
488.60	0938-0360.
489.20	0938-0667.
489.21	0938-0357.
489.24	0938-0667.
489.27	0938-0692.
489.28	0938-0713.
489.40-41	0938-0383.
489.66, 489.67	0938-0713.
489.102	0938-0610.
491.1-11	0938-0074.
491.2	0938-0685.
491.9	0938-0334.
493.1-2001	0938-0151, 0170, 0544, 0581, 0612 and 0653.
493.501, 493.506, 493.513, 493.515	0938-0686.
493.1840	0938-0655.
498.40-95	0938-0486 and 0567.
1003.100, 1003.101, 1003.103	0938-0700.
1004.40, 1004.50, 1004.60, 1004.70	0938-0444.
45 CFR:	
96.70-74	0938-0481.
146.111, .115, .117, .150, .152, .160, .180	0938-0702.

	OMB control Nos.
148.120, .122, .124, .128	0938-0703.

Dated: April 28, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute: VHL and MET Mutation Detection Technology: Opportunities for Cooperative Research and Development Agreements (CRADAs) for the Joint Evaluation and Development of Methods to Detect Mutation in Both Gene Sequences Using Nucleic Acid Array Technology

The methods may include but are not limited to spectroscopic partitioning techniques and DNA chip technology. The NCI is looking for multiple CRADA Collaborators to develop independently different aspects of this VHL and MET mutation detection technology.

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

ACTION: Notice for CRADA Opportunities.

SUMMARY: Pursuant to Federal Technology Transfer Act of 1986 (FTTA, 15 U.S.C. 3710; and Executive Order 12591 of April 10, 1987, as amended by the National Technology Transfer and Advancement Act of 1995), 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 Cooperative Research and Development Agreements (CRADAs) with pharmaceutical or biotechnology companies to evaluate and develop methods to detect mutations in both the MET and VHL gene sequences using nucleic acid array technology. Any CRADA for the biomedical use of this technology will be considered. The CRADAs would have an expected duration of one (1) to five (5) years. The goals of the CRADAs include the rapid publications of research results and timely commercialization of products, diagnostics and treatments that result from the research. The CRADA

Collaborators will have an option to elect a non-exclusive or exclusive commercialization license to subject inventions arising under the CRADAs that are related to the DNA array technology of the collaborators, which are the subject of the CRADA Research Plan, for diagnostics and research supply and can apply for background licenses to the existing patents listed below, subject to any pre-existing licenses already issued for other fields of use. Licensing by NIH is subject to 35 U.S.C. 207 and 37 CFR Part 404.

ADDRESSES: Proposals and questions about this CRADA opportunity may be addressed to Dr. Thomas M. Stackhouse, Technology Development & Commercialization Branch, National Cancer Institute-Frederick Cancer Research & Development Center, Fairview Center, Room 502, Frederick, MD 21701 (phone: 301-846-5465, fax: 301-846-6820).

Scientific inquiries—Dr. Berton Zbar, Chief, Laboratory of Immunobiology, National Cancer Institute-Frederick Cancer Research & Development Center, P.O. Box B, Building 560, Room 12-68, Frederick MD, 21702-1201 (phone: 301-846-1288 FAX: 301-846-6145).

EFFECTIVE DATE: Inquiries regarding licensing and scientific matters may be forwarded at any time. Confidential CRADA proposals, preferably one page or less, must be submitted to NCI on or before July 6, 1998. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents who have been selected.

SUPPLEMENTARY INFORMATION:

Technology Available

DHHS scientists have identified mutations in the proto-oncogene c-MET, and the von Hippel-Lindau disease (VHL) tumor suppressor gene in human cancers. c-MET is the receptor for hepatocyte growth factor/scatter factor. Germline mutations in the MET gene have been detected in affected members of families with an inherited predisposition to develop papillary renal carcinomas; somatic mutations in the MET gene have been detected in a subset of papillary renal carcinomas. All mutations detected in the MET gene to date were located in the tyrosine kinase domain; all mutations were missense.

The VHL gene is mutated in patients with von Hippel-Lindau disease, and in sporadic clear cell carcinomas of the

kidney. Disease-causing mutations include gender deletions (partial or complete), missense and nonsense and frame shift mutations.

About 30,000 individuals develop kidney cancer each year. We anticipate that the novel mutation detection techniques for the MET and VHL genes will be used in patients with sporadic and inherited predispositions to renal cancer. Possible uses would include diagnosis and prognosis of kidney cancer. In addition, these new methods might be applied to the study of other types of human neoplasia.

DHHS now seeks collaborative arrangements for the joint evaluation and development of methods to detect mutations in both gene sequences using nucleic acid array technology. The methods may include but are not limited to spectroscopic partitioning techniques and DNA chip technology. For collaborations with the commercial sector, a Cooperative Research and Development Agreement (CRADA) will be established to provide equitable distribution of intellectual property rights developed under the CRADA. The successful CRADA partner will collaboratively develop and test known mutations within the genes from samples provided by the government. CRADA aims will include rapid publication of research results as well as full and timely exploitation of any commercial opportunities.

NCI's VHL/MET Patents and Patent Applications

1. Von Hippel-Lindau (VHL) Disease Gene and Corresponding cDNA and Methods for Detecting Carriers of the VHL Disease Gene; United States Patent 5,654,138, issued August 5, 1997.

The role of the National Cancer Institute in this CRADA will include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise and experience to the research project.
2. Providing the Collaborator with samples of the subject gene sequences for evaluation.
3. Planning research studies and interpreting research results.
4. Publishing research results.

The role of the CRADA Collaborator may include, but not be limited to:

1. Providing significant intellectual, scientific, and technical expertise or experience to the research project.
2. Planning research studies and interpreting research results.