

information collection requirement concerning GSAR Clause, Qualifications of Employees. Information collected under this authority is required by regulation. A request for public comments was published at 67 FR 330, January 3, 2002. No comments were received.

Public comments are particularly invited on: Whether this information collection generated by the GSAR Clause, Qualifications of Employees, is necessary for security reasons, to properly determine if an employee is suitable to work under a GSA service contract for guards, child care, cleaning, and maintenance contract; whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

**DATES:** April 24, 2002.

**ADDRESSES:** Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Ms. Jeanette Thorton, GSA Desk Officer, OMB, Room 10236, NEOB, Washington, DC 20503, and a copy to Ms. Stephanie Morris, General Services Administration (MVP), Room 4035, 1800 F Street, NW., Washington, DC 20405.

**FOR FURTHER INFORMATION CONTACT:** Julia Wise, Acquisition Policy Division, GSA (202) 208-1168.

**SUPPLEMENTARY INFORMATION:**

**A. Purpose**

The General Services Administration has various mission responsibilities related to the acquisition and provision of service contracts. These mission responsibilities generate requirements that are realized through the solicitation and award of service contracts for guards, childcare, cleaning, and maintenance. Individual solicitations and resulting contracts may impose unique information collection/reporting requirements on contractors, not required by regulation, but necessary to evaluate particular program accomplishments and measure success in meeting program objectives.

**B. Annual Reporting Burden**

*Respondents:* 15,496.

*Responses Per Respondent:* 1.

*Total Responses:* 15,496.

*Hours Per Response:* 1.

*Total Burden Hours:* 15,496.

**Obtaining Copies of Proposals**

A copy of this proposal may be obtained from the General Services Administration, Acquisition Policy Division (MVP), Room 4035, 1800 F Street, NW., Washington, DC 20405, or by telephoning (202) 501-4744, or by faxing your request to (202) 501-4067. Please cite OMB Control No. 3090-0006, Qualifications of Employees, in all correspondence.

Dated: March 19, 2002.

**Michael W. Carleton,**

*Chief Information Officer (I).*

[FR Doc. 02-7138 Filed 3-22-02; 8:45 am]

**BILLING CODE 6820-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Secretary's Advisory Committee on Genetic Testing; Request for Public Comment**

**AGENCY:** Office of the Secretary, DHHS.

**ACTION:** Request for public comment on a draft information brochure on genetic tests for the general public.

**SUMMARY:** The Secretary's Advisory Committee on Genetic Testing (SACGT) is seeking public comment on a draft information brochure entitled *Genetic Testing: Some Basic Questions and Answers*. The content of the brochure is reproduced below. The brochure's objective is to provide an overview of genetic tests and to outline some questions to consider about having a genetic test. Its target audience is the general public.

**DATES:** The public is encouraged to provide written comments on the draft brochure by April 19, 2002. Comments may be sent by mail (SACGT, National Institutes of Health, Office of Biotechnology Activities, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892), facsimile (301-496-9839), or email ([sc112c@nih.gov](mailto:sc112c@nih.gov)). All public comments received will be available for public inspection at the SACGT office between the hours of 8:30 a.m. and 5:00 p.m.

**FOR FURTHER INFORMATION CONTACT:** Questions about this request can be directed to Ms. Sarah Carr, SACGT Executive Secretary, by e-mail, [sc112c@nih.gov](mailto:sc112c@nih.gov), or telephone (301-496-9838). The draft brochure also will be posted on SACGT's website for review and comment.

**SUPPLEMENTARY INFORMATION:**

Ensuring the appropriate use of genetic tests is an important challenge, requiring dedicated efforts on several fronts, including public education. A well-informed public will have a basic understanding about the benefits, risks, and implications of genetic tests and, should the situation arise, will know what questions to ask to make an informed decision about whether to have a genetic test. SACGT has developed the following draft information brochure, *Genetic Testing: Some Basic Questions and Answers*, to help inform the general public about genetic tests and to suggest the type of questions they should consider asking if they are faced with a decision about whether to have a genetic test.

Using a question and answer format, the brochure explains what genetic tests are, the different purposes for which they are used, how they are similar to and different from other medical tests, and some of their limitations and possible outcomes (potential benefits and risks); addresses insurance policy implications, privacy, confidentiality, and discrimination; provides informational and services resources; and outlines questions to ask oneself and one's healthcare provider when considering a genetic test. The brochure does not provide information about specific genetic tests nor is it intended for patients or consumers who have had experience with genetic testing.

SACGT is seeking comments on the content, readability, and utility of the brochure and strategies for dissemination. In particular, SACGT would appreciate responses to the following specific questions:

1. Is the document useful? How might you use such a brochure?
2. Is the content appropriate and complete? Is it understandable and written at the appropriate reading level? Are there other issues that should be addressed? Are there other questions that should be included?
3. Is the tone of the brochure appropriate? Is it culturally appropriate to a wide range of groups?
4. Should the brochure be produced in other languages and, if so, which languages?
5. To whom and how should this brochure be disseminated?
6. Should the brochure serve as a model for the development of more specific test information brochures? Who should be tasked with developing such brochures? Is this an appropriate role for SACGT? Should SACGT recommend that HHS support the development of test-specific information brochures?

## Draft Brochure

### *Genetic Testing: Some Basic Questions & Answers*

Genetic tests have been available for a number of years, but more tests are becoming available and are being offered as part of medical care. At some point in the future, you may face a decision about whether to have a genetic test.

Genetic tests are like other medical tests in many ways, but they have some important differences and issues to consider. This brochure provides some basic information about genetic testing and highlights the kinds of questions you may want to ask.

#### What is a Genetic test?

(To include diagram of chromosomes, genes, gene products)

Our genetic information is contained in structures called chromosomes that are made up of a chemical called DNA. Chromosomes are made up of smaller units called genes. There are 23 pairs of chromosomes, one set from our father and one from our mother. Genes contain the information about how our bodies are put together and function. It may help to think of the chromosome as a necklace and genes as beads on the necklace.

Genetic tests usually involve having blood drawn to look for changes in DNA, genes, gene products, or chromosomes. Some changes, such as those that cause certain cancers, develop during one's lifetime, possibly through environmental factors like sun exposure. Other changes can be inherited from one or both parents and passed on to children.

#### What Are the Different Types of Genetic Tests?

■ *Diagnostic tests* are used to diagnose a medical condition in people who have symptoms or health problems. Diagnostic tests can also be used to figure out the best course of treatment or how a medical condition might progress over time.

■ *Predictive tests* are used to tell whether healthy people are at higher risk of developing a particular medical condition later in life.

■ *Pharmacogenetic tests* are used to tell how genetic makeup may affect a person's reaction to specific medicines. This type of test may help healthcare providers prescribe the most effective drugs with the fewest side effects.

■ *Newborn screening tests* are done when babies are born to tell whether they have certain genetic diseases. These are diseases that can be treated

if they are found early enough. By state law or rules, all babies are screened unless the parents decline testing.

■ *Carrier tests* are used to tell whether healthy people have one copy of a genetic change that puts their children (but not them) at higher risk for having a genetic condition.

■ *Prenatal tests* diagnose genetic conditions in pregnancy.

#### Are Genetic Tests Different From Other Medical Tests?

Genetic tests are similar to other medical tests, but there are a couple of important differences to keep in mind. Medical tests generally provide information only about the person being tested. Genetic test results can provide information for the health or life decisions of other family members as well.

Medical tests usually look for a current health condition. Predictive genetic tests, on the other hand, are done when people are healthy to see whether they are at higher risk of developing a particular disease in the future.

Unlike most other medical tests, genetic education and counseling may be provided for some genetic tests to be sure that patients understand the test, the potential results, and issues to consider.

#### What Are Some Limitations of Genetic Testing?

Like other medical tests, genetic tests have limitations, and they differ depending on the type of genetic test. For example, predictive genetic tests do not give "yes" or "no" answers about whether you will develop a specific disease. Instead, they tell you what your chances might be of developing a medical condition. They do not establish for sure that you will develop the condition or how the condition will affect you.

A genetic test does not test for all genetic conditions. Rather, a genetic test is done for a specific genetic condition or group of genetic conditions. In addition, for some diseases, a genetic test may not detect all changes that cause a specific condition. If the test does not find a change, you could still have or be at risk for that condition or be at risk for having children with that condition. For some tests, a family member with the condition may need to be tested to identify the genetic change before other family members who may be at risk can be tested.

Your healthcare provider, genetic specialist, or a testing laboratory can provide more information about test

limitations. Over time, additional research may reduce some of the current uncertainties with genetic tests.

#### What Are Some of the Risks and Benefits of Having a Genetic Test?

Each genetic test has different risks and benefits. In general, the risks of genetic tests are not physical, since they mostly involve routine procedures, such as drawing blood or swabbing a cheek. Instead, the benefits and risks have more to do with how prepared you and your family are to learn the results. Learning that you may be at higher risk for a disease, for example, may be difficult to handle emotionally. On the other hand, the knowledge may help you plan preventive measures or make better decisions about the future. Likewise, you may learn that you are healthy, but members of your family have a higher likelihood of disease. For these reasons, it is important to weigh carefully the possible positive and negative outcomes before deciding whether or not to have a genetic test.

#### Possible Benefits of Genetic Testing

- You may learn information that is important for your healthcare.
- *You may learn that you have or are at risk for a medical condition.* The results of genetic testing may be useful for diagnosing a medical condition or predicting risks for conditions. The results may help predict the course of the disease or determine a treatment plan, screening options, or prevention strategies. Results of genetic tests could also be important for family members if they are at risk for the same medical condition.
- *You may learn that you are not at increased risk for a medical condition.* Such information may give peace of mind. However, many conditions are caused by your environment, diet, or behavior, as well as genetics. You may still face the same odds of getting such a condition as the population at large.
- *You may learn that you are a carrier for a medical condition.* You may have a disease-causing gene but not have the condition yourself. If your partner is a carrier too, you could have children with the genetic condition. If you find out that you are a carrier, your partner may want to be tested prior to having children to see if he or she is also a carrier. If you are a carrier of a genetic condition, your relatives may be carriers too, and they may also want to be tested.
- You may learn information that could be useful for future decision

making.

Finding out whether you have, or are at risk for, a particular genetic condition may be important information for your life decisions. If you decide to have children, you may want to undergo prenatal testing or prepare for a child with special needs. The results of a genetic test may also have an impact on your financial planning, career choices, and lifestyle.

- Test results may provide relief and reduce anxiety and uncertainty about the future.

Finding out that you are not at risk for a particular medical condition can bring a sense of relief and peace of mind. Sometimes, even people who learn that they have, or may develop, a genetic condition feel less anxious after learning their test results. They may experience more anxiety from “not knowing” than “knowing” their risk. For others, the reverse may be true.

#### Potential Risks of Genetic Testing

- You may learn information that can be difficult to handle.

Coping with the knowledge from genetic tests may be difficult. It is particularly hard if there is no treatment or cure for the medical condition or if the condition may not develop until later in life. It is not unusual for people to feel sad, angry, confused, or anxious. Talking these feelings over with your healthcare provider or a genetics specialist may help. You may also find support from therapists, religious leaders, your friends and family, and patient/consumer advocacy or support groups (listed under “Informational Resources”).

- Family dynamics may change.

Genetic conditions may affect family members in different ways. Sharing medical information in a family and addressing feelings can sometimes be difficult and may change how family members relate to each other. It is important to keep in mind that there are supportive resources (some of which are listed below) that can help.

- The result may not be clear or uncertain.

There are limitations to today’s testing technology. Sometimes a test may not produce a definite result. At other times, the meaning of a test result may not be known. Even after having a genetic test, you may not learn anything new or may be left with uncertainty about what a result means. Of course, the field of genetic testing is changing, so tests will become more refined over time.

- You may be at risk for insurance or employment discrimination.

People are often concerned that the results of genetic tests could be used by

insurers to deny coverage or increase the cost of insurance. They also worry that employers might use the test results in hiring and promotion decisions. The way insurers use test results generally depends on the type of plan you have, such as whether it is individual or group coverage. There are some protections to help prevent such discrimination, and they are discussed in the next section.

#### Can the Results of Genetic Testing Affect Insurance Coverage or Employment?

Some states prohibit employers from using genetic information in hiring and promotion decisions. Some prohibit health insurers from increasing fees or denying coverage based on genetic information. There are also significant differences among states in the level of protection. In other words, the results of genetic tests could affect your coverage depending on the type of insurance you have, whether or not you have symptoms, and the state in which you live. You can find out about your state’s laws by contacting the National Conference of State Legislatures at 303–830–2200 or [www.ncsl.org](http://www.ncsl.org). The National Human Genome Research Institute also posts information about current state laws, as well as information about federal efforts, at: [http://www.nhgri.nih.gov/Policy\\_and\\_public\\_affairs/Legislation/](http://www.nhgri.nih.gov/Policy_and_public_affairs/Legislation/)

#### Will Test Results Be Kept Confidential?

Your medical records, including genetic test results, are confidential. Test results can only be released with your permission or unless specifically required by law. The terms of most health insurance policies give the insurance company access to your medical information, especially if you request insurance coverage of genetic testing. However, many companies have policies stating that your health information will not be shared without your consent. You have the right to see the information in your medical records.

#### Will Insurance Cover the Cost of Genetic Testing?

Insurance coverage for genetic testing will depend on the type of insurance you have and the indication for testing. Genetic tests can cost more than other tests because they can take longer to perform and the techniques are more complex. If your insurance does not cover the cost of genetic testing, you may have to pay out-of-pocket. Find out about the cost of the test and insurance coverage before having the test done.

#### Where Can I Find More Information About Genetic Disorders or Genetic Testing?

Patient and consumer advocacy or support groups can help you obtain information about genetics and specific genetic conditions. They can also help you make connections with people facing similar issues. In addition, many government agencies have helpful resources.

#### Informational Resources

- Genetic Alliance, Toll free number: 800–336–4363. ([www.geneticalliance.org](http://www.geneticalliance.org)).
  - Genetics Education Center, ([www.kumc.edu/gec/](http://www.kumc.edu/gec/)).
  - “GeneTests”, (<http://www.genetests.org/>).
  - March of Dimes, Toll free number: 888–663–4637. ([www.modimes.org](http://www.modimes.org)).
  - National Human Genome Research Institute, ([http://www.nhgri.nih.gov/Policy\\_and\\_public\\_affairs/Communications/Patients\\_and\\_families/](http://www.nhgri.nih.gov/Policy_and_public_affairs/Communications/Patients_and_families/)).
  - National Newborn Screening and Genetics Resources Center, ([www.genes-r-us.uthscsa.edu](http://www.genes-r-us.uthscsa.edu)).
  - National Organization for Rare Disorders, Toll free number: 800–999–6673. ([www.rarediseases.org](http://www.rarediseases.org)).
  - Office of Rare Diseases, National Institutes of Health, (<http://rarediseases.info.nih.gov/ord/>).
  - Office of Genetics and Disease Prevention, Centers for Disease Control and Prevention, (<http://www.cdc.gov/genetics/default.htm>).
  - U.S. Department of Energy, (<http://www.ornl.gov/hgmis/medicine/genetest.html>).
- Genetics clinics provide care, information and support for individuals who have, or are at risk for, a genetic condition.
- To locate genetic services, you can:
- Ask your healthcare provider
  - Contact your local medical center/hospital and ask if there are genetic services
  - Contact your state department of public health and request information on genetic services
  - Contact the National Society of Genetic Counselors (610–872–7608) [www.nsgc.org](http://www.nsgc.org)
  - Contact the Genetic Alliance (toll free: 800–336–4363) [www.geneticalliance.org](http://www.geneticalliance.org)
  - Contact your local March of Dimes chapter (888–663–4637) [www.modimes.org](http://www.modimes.org)
  - For cancer genetics specialists, contact the National Cancer Institute (toll free: 800–422–6237) [www.nci.nih.gov](http://www.nci.nih.gov)

## To Be Placed at the End of the Document as a Tear-Out Page

### Questions to Ask About Genetic Testing

Below are some questions you can ask yourself and your healthcare provider as you consider genetic testing. Many of these same questions could be asked about any medical test. There may not be answers to all of these questions and some of the answers may change as our knowledge about genetic testing grows.

#### Questions to Ask Yourself

- Do I know what type of genetic test is being offered?
- Will the test results be helpful to me? Do I want to know this information?
- What might I do differently if I have the results?
  - Will I make changes in my healthcare based on the results?
  - Will I make changes in my life decisions (e.g. children, finances, career choice) based on the results?
- Is this a good time in my life for me to have the genetic test?
- What will my reactions be when receiving the genetic test results?
- Do I have the support that I may need or people who I can talk to, if needed?
- Have I given myself enough time to explore these issues?
- Do I have all the information I need to make a decision about genetic testing? Have all my questions been answered?

#### Questions to Ask Your Healthcare Provider

- Specific genetic test and purpose:* What genetic test(s) will be done? What is the purpose of doing the genetic test? Why is the genetic test recommended?
- Test accuracy & limitations:* How accurate is the genetic test? What are the limitations of the genetic test? How well does the test diagnose or predict the medical condition? Does the laboratory where the test will be performed have the appropriate certification?
- Benefits & risks:* What are the benefits and risks of being tested? Of not being tested?
- Result interpretation:* What are the possible test outcomes and what will the results mean?
- Communication of results:* When can I expect to receive my test results? How will results be communicated to me?
- Medical care:* What are the signs and symptoms of this condition? Are there medical treatments or preventive options available for the condition? Would options change

depending on the test results? What would my options be if I decide not to be tested?

- Insurance issues:* What is the cost of the genetic test(s)? Will my insurance cover the cost? Will the results of genetic testing affect my insurance rates, coverage or my ability to obtain insurance?
- Confidentiality of test results:* Who will have access to my test results? Will the results be kept confidential?
- Family issues:* What will my test results mean for other family members? Should other family members consider genetic testing? What should I tell my family members?
- Sample issues:* Will part of my sample be left over from the test and, if so, what will happen to it?

#### Genetic Testing—It Should Be Your Decision

This brochure has provided some basic information about genetic testing. We hope it will be helpful if you have to make decisions about genetic testing. Some people may decide to have a genetic test because they feel the information would be important for their healthcare and/or life decisions. Others may decide not to have a genetic test because they feel that the risks outweigh the benefits of having the information, they feel their decisions would be no different, or they prefer not to know. The decision to have a genetic test is yours to make. It's your genetic information, and it's your choice.

Dated: March 18, 2002.

**Sarah Carr,**

*Executive Secretary, SACGT.*

[FR Doc. 02-7056 Filed 3-22-02; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; Comment Request; Agricultural Health Study (A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture)—Validation Sub-Study, on Rheumatoid Arthritis

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection

listed below. This proposed information collection was previously published in the **Federal Register** on Tuesday, October 23, 2001, pages 53618-53619 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:* Agricultural Health Study (A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture)—validation sub-study on Rheumatoid Arthritis.

*Type of Information Collection*

*Request:* Revision of a currently approved collection (0925-0406, expiration 11/31/03).

*Need and Use of Information*

*Collection:* The Agricultural Health Study is an ongoing prospective cohort study of 89,189 farmers, their spouses, and commercial applicators of pesticides from Iowa and North Carolina. The proposed collection of additional information is intended to assess the validity of self-reported Rheumatoid Arthritis (RA) in the Agricultural Health Study (AHS) within small subgroups of individuals. The collection is intended to identify confirmed cases of RA to include in etiologic analyses of farming exposures and RA; evaluate the efficacy of certain questions or sets of questions for screening out false-positives for self-reported RA and identify subgroups to target for future etiologic studies of RA, based on a relatively high prevalence of RA and the feasibility of disease confirmation.

*Frequency of Response:* Single time reporting.

*Affected Public:* Individuals or households, Farms.

*Type of Respondents:* Private pesticide applicators and their spouses. The annual reporting burden is as follows:

*Estimated Number of Respondents:* 11,373..

*Estimated Number of Responses per Respondent:* 2.2;

*Average Burden Hours Per Response:* 1.18.

*Estimated Total Annual Burden Hours Requested:* 13,433.

*The annualized cost to respondents is estimated at:* \$138,045. There are no Capital Costs to report. There are no