**Supporting Statement A for:**

National Institute of Nursing Research (NINR)
Summer Genetics Institute Alumni Survey

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**List of Attachments**

Attachment 1: Summer Genetics Institute Alumni Survey

Attachment 2: Summer Genetics Institute Alumni Survey screen shots

Attachment 3: Introductory, Invitation, Reminder, and Thank You Emails

Attachment 4: Informed Consent

Attachment 5: NIH Privacy Act Officer’s Letter

Attachment 6: IRB Statement

Attachment 7: Summer Genetics Institute pilot survey analysis

A. Justification

## A.1 Circumstances Making the Collection of Information Necessary

The National Institute of Nursing Research (NINR) supports and conducts clinical and basic research and research training on health and illness across the lifespan. The research focus encompasses health promotion and disease prevention, quality of life, health disparities, end of life care, and research training. NINR’s activities are authorized under 42 USC 285q, wherein it is stated:

 “The general purpose of the National Institute of Nursing Research (in this subpart referred to as the "Institute") is the conduct and support of, and dissemination of information respecting, basic and clinical nursing research, training, and other programs in patient care research.”

The National Institute of Nursing Research (NINR) Summer Genetics Institute (Summer Genetics Institute) is a summer training program for nursing scientists that is designed to provide a foundation in molecular genetics for use in clinical practice and the research laboratory. This program began in 2000 and has been held in all subsequent years.

The purpose of the Summer Genetics Institute is to increase the genetics research capability among graduate students and faculty, and develop and expand the basis for clinical practice in genetics among clinicians.

The short-term goals of Summer Genetics Institute are to:

* Increase knowledge in molecular genetics for use in research, teaching, and clinical practice.
* Identify the strengths, weaknesses, and applications of genetic tests and inaccuracies that can be introduced during the testing period.

Long-term goals include:

* Using molecular genetics methods for biobehavioral research.
* Analyzing strategies used for genomic-based therapies and trends in molecular therapeutics.
* Analyzing ethical and legal issues related to genetic testing and genetic counseling and implications for practice and research.
* Evaluating families with genetic problems and make appropriate referrals to genetic and community resources.

The purpose of the Summer Genetics Institute Alumni Survey is to examine the extent to which the Summer Genetics Institute is achieving its long-term goals in research and clinical practice by increasing genetics research capability, so that changes to the program can be made if indicated.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), NINR is requesting clearance from the Office of Management and Budget (OMB) to conduct a data collection procedure as part of evaluation of the NINR Summer Genetics Institute. Specifically, clearance is requested for a 39-item Web-based survey of Summer Genetics Institute alumni to be administered annually.

## A.2 Purpose and Use of the Information

The purpose of the Summer Genetics Institute Alumni Survey is to collect prospective data on the long-term outcomes of this training program. This information will be used to refine the Summer Genetics Institute so that career objectives of Summer Genetics Institute Alumni related to genetics research and education can be met.

## A.3 Use of Improved Information Technology and Burden Reduction

In an effort to minimize the burden of data collection, responses will be collected through a Web-based survey, which will permit electronic submission. Since Summer Genetics Institute alumni have known e-mail addresses and are likely to have access to the Internet, the Web-based questionnaire will be an easy and convenient mechanism to use. Respondents will be able to click on a URL within an invitation e-mail which will direct them to the questionnaire Web site.

Online administration of the questionnaire is efficient because the respondent will enter the data directly into the database, avoiding the separate step of key entry of paper questionnaire data into a database. The cleaning of the data will also be facilitated through online administration.

An email notification letter and an invitation letter (see Attachment 3) will be sent to Summer Genetics Institute alumni. The notification letter will inform the Summer Genetics Institute alumni about the survey. The invitation email will inform the Summer Genetics Institute alumni about the importance of their participation in the evaluation. In addition, the invitation email will indicate that the study is conducted by the National Institute of Nursing Research of the National Institutes of Health and will succinctly inform readers of the purpose and importance of the questionnaire, the confidentiality of the data, the procedures for maintaining the privacy of respondents, and that response is voluntary. The email will include a URL link to a secure website where the Summer Genetics Institute alumni can complete the survey.

A Privacy Impact Assessment (PIA) was done for the database being used to collect this information and approved by Karen Pla, NIH Senior Official for Privacy on September 28, 2012.

## A.4 Efforts to Identify Duplication and Use of Similar Information

The Summer Genetics Institute Alumni Survey has not previously been used in this population. There is no similar information available for use. No other questionnaire or data could provide the information required for the proposed study.

## A.5 Impact on Small Businesses or Other Small Entities

No small businesses or other small entities will be involved in this study.

## A.6 Consequences of Collecting the Information Less Frequently

The Summer Genetics Institute Alumni Survey will be repeated annually for 3 years. The rationale for this collection method is to gather information about how participation in the Summer Genetics Institute has influenced career trajectory over time.

## A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

 No special circumstances are anticipated. This information collection fully complies with 5 CFR 1320.5(d) (2).

## A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

As required by 5 CFR 1320, a 60-day notice of this proposed data collections was published in the Federal Register, Volume 77, Number 126, Page 38840 on June 29, 2012, and allowed 60-days for public comment. No public comments were received.

Outside consultation was conducted with a public health consulting firm (Discovery Logic – a Thomson Reuters business) who has expertise in health research and survey methodology, to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format, and on the data elements to be recorded, disclosed, or reported. The following individuals provided us with comments and suggestions on the NINR Summer Genetics Institute Alumni Survey for clearance:

* Unni Jensen, PhD, PMP (office telephone: 301-545-4289; email: unni.jensen@thomsonreuters.com)
* Margaret Metzger (office telephone: 301-545-4227; email: peggy.metzger@thomsonreuters.com).
* Christy Hyatt, BS (office telephone 301-545-4116; email: christy.hyatt@thomsonreuters.com)
* Jodi Simco, PhD (office telephone 703-841-3111; email: Jodi.Simco@haygroup.com)

## A.9 Explanation of Any Payment or Gift to Respondents

Participants responding to this questionnaire will not receive remuneration for their participation.

## A.10 Assurance of Confidentiality Provided to Respondents

Information provided by the respondents will be kept private to the extent permitted by law. This information will be communicated to respondents by means of an introductory email letter and invitation and reminder email that includes information about the questionnaire (Attachment 3).The beginning of the web-based survey includes information about privacy (Attachments 1 and 2). NINR and its contractor, Discovery Logic, will follow best practices to maximize privacy and security of all data.

Respondents will be assigned a confidential ID number. Personal identifying information will be stored separately from responses. Files will be kept in a secure environment and no one outside of this study will have access to them. NINR and its contractor will use contact information for requesting subject participation and for subsequent follow-up in the case of non-response.

An informed consent form will be shown to all potential study participants before they start the survey. The form describes the purpose of the survey and the confidentiality of the data. Participants will be prompted to accept or decline participation by selecting the appropriate button at the bottom of the electronic form. By giving consent, participants indicate that they have read the form, understand what they are consenting to, and are aware of their rights as research participants. The consent form will state the following:

* The questionnaire is sponsored by the National Institute of Nursing Research, part of the National Institutes of Health.
* Reports will be used to improve the Summer Genetics Institute and measure the influence of the Summer Genetics Institute on career trajectory.
* Information provided by respondents will be kept private. Personal identifying information will be used only by researchers following up with respondents; identifying information will not be disclosed except as required by law.
* Response to the survey is voluntary, and there are no penalties for not responding to the information collection as a whole or to any particular questions.
* In order to protect respondents’ privacy, all presentation of data in reports will be in aggregate form, with no links to individuals preserved.

The information collected in this study is covered by NIH Privacy Act Systems of Record 09‑25‑0156, “Records of Participants in Programs and Respondents in Questionnaires Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD” (<http://oma.od.nih.gov/ms/privacy/pa-files/0156.htm> (see Attachment 5 for NIH Privacy Act Officer’s Letter). Dr. Pursely-Crotteau from the NIH Office of Human Subjects Research Protections wrote that since this survey is part of a program evaluation that IRB approval is not required. A copy of this communication is found in Attachment 6.

## A.11 Justification for Sensitive Questions

No questions of a sensitive nature will be asked. Questions are of a general nature and disclosure would not create harm to individuals. Never the less data will be kept private and information will be reported in the aggregate rather than attributed to specific individuals. All respondents have the right not to answer a particular question or to stop their participation at any time without any consequence.

## A.12 Estimates of Annualized Burden Hours and Costs

Response burden estimates are shown in Table A-12-1. The average time for completing the Summer Genetics Institute Alumni Survey is 30 minutes. From the beginning of the Summer Genetics Institute in 2000 through 2010, 230 individuals have completed the Summer Genetics Institute. In addition, 25 new Summer Genetics Institute participants are accepted into the program each year. New alumni will be invited to complete the survey. By the end of 2014, the total number of expected alumni is 305. A response rate of 50% is expected. This response rate is expected because over half of the alumni have applied for research and training grants at the National Institutes of Health since attending Summer Genetics Institute. **In addition, most Summer Genetics Institute alumni have self-identified as researchers in the application to participate in the Summer Genetics Institute.** The total annual burden is estimated to be 75 hours (see Table A-12-1).

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| **Table A-12-1 Estimates of Annual Burden Hours** |
| **Type of Respondents** | **Number of Respondents** | **Frequency of Response** | **Average Time per Response** **(in hours )** | **Total Burden Hours** |
| Researchers | 150 | 1 | 30/60 | 75 |

The total annual cost to respondents is estimated at $3159.75 as shown in Table A-12-2. Annualized costs were calculated using the mean hourly wage provided by U.S. Department of Labor, Bureau of Labor Statistics, Occupation Employment and Wages, May 2011, 19-1042 Medical Scientists, Except Epidemiologists (available at <http://www.bls.gov/oes/current/oes191042.htm>) [[1]](#footnote-1)mean hourly wage. Respondents to this questionnaire are nurse researchers who conduct research dealing with the understanding of human diseases and the improvement of human health and engage in clinical investigation, research and development, or other research related activities, nurse educators, and nurse clinicians including nurse practitioners.

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| **Table A-12-2: Annualized Cost to Respondents** |
| **Type of Respondents** | **Number of Respondents** | **Frequency of Response** | **Average Time per Response** **(in hours)** | **Hourly Wage Rate** | **Total Respondent Cost** |
| Nurse Researchers, Educators, and Clinicians | 150 | 1 | 30/60 | $42.13 | $3159.75 |

## A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital or startup costs for the data collection efforts requested; nor are there any costs associated with operation, maintenance, or purchase of services.

## A.14 Annualized Cost to the Federal Government

The estimated annualized cost to the government to conduct and analyze this annual survey for three years is $21,478. The budget includes the costs of survey design and development, all data collection and follow-up, date file preparation and documentation, initial analyses, and other miscellaneous costs such as supplies and expenses. Professional service time is included for study management and overhead costs. The annualized government cost distribution is summarized in the Table A-14-1.

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| **Table A-14-1 Annualized Government Cost Distribution** |
|  | **Estimated Costs** |
| Contractor Costs | $15,469 |
| Survey Maintenance | $3,578 |
| Analysis | $2,431  |
| **Total** | **$21,478** |

Annualized **Contractor Costs of $15,469: These costs include the following tasks to be completed by the contractor: assist with development and refinement of survey items, develop/program Web-based questionnaire including response options, skip patterns, and data repository, testing of web-based questionnaire prior to pilot, pilot testing of questionnaire and cognitive interview with pilot participants, and reporting pilot test findings. These costs also include administering questionnaire (i.e., introductory, invitation, reminder, and thank you emails), and preparing database with responses for analysis for the first year when the survey is administered. (Note: Administering and analyzing the survey in years two and three will be done by NINR staff.) The following contract personnel expertise are required to perform these tasks: contract project manager, survey/evaluation experts, and Web developer/programmer.**

**Annualized survey maintenance of $3,578: This survey will be hosted on an NIH server which requires secure maintenance by NIH staff. This maintenance is estimated to take 88 hours per year for 3 years by a GS 12 Information Technology (IT) staff.**

**Annualized analysis costs of $2,431: This includes organizing and cleaning data, conducting statistical analysis of the data, drafting the findings report including required grafts and tables, and writing the final report of findings. This task requires expertise in evaluation, surveys, statistics, and science writing with management by the contractor project manager. Analysis will be done by contractor and NINR staff and is estimated to take 40 hours by an analyst (GSA 13) with 10 hours review by a senior evaluator (GSA 14). During year 1, the analysis will be conducted by the contractor (estimated 40 hours) with review (10 hours) by a senior evaluator. In years 2 and 3, analysis will be conducted by an NINR analyst (GSA 13 estimated 40 hours) with 10 hours review by a senior evaluator (GSA 14).**

## A.15 Explanation for Program Changes or Adjustments

This is a new collection of information.

## A.16 Plans for Tabulation and Publication and Project Time Schedule

The plan is to begin the questionnaire one month after OMB approval has been received. The project schedule for completing data collection, processing, and during the first year of collection is presented in Table A-16-1. Each subsequent year of data collection from Summer Genetics Institute alumni will follow the same schedule.

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| **Table A-16-1. Project Time Schedule** |
| **Activity** | **Estimated Time Schedule after OMB approval** |
| Introductory email  | 1 month |
| Initial email invitations  | 1.25 months |
| Follow-up emails | 1.75 months |
| Completion of data collection | 2 months |
| Analysis of data | 3 months |
| Preliminary report | 4 months |
| Final annual report | 4.5 months |

This survey will obtain data from the Summer Genetics Institute alumni. Sources of information will be combined to analyze overall Summer Genetics Institute career paths and linkages between the data collected. Quantitative data analysis will include descriptive analyses. Descriptive statistics will be used to describe the number and type of career activities including types of research, educational, and clinical job positions, continued education and research training, research grant activities, and publications.

**Descriptive Statistics.** Table A. 16 – 2 indicates an example of descriptive data that could provide important guidance as to what types of research grants are applied for and awarded to Summer Genetics Institute alumni. For example, we will examine the proportions of research grants awarded for genetic related studies compared to other types of research studies.

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| **Table A. 16-2 Percent of Summer Genetics Institute with research grant awards by research study type** |
| **Agencies** | **Percent of Sample** |
| Genetics related research |  |
| Non-genetics research |  |

## A.17 Reason(s) Display of OMB Expiration Date Is Inappropriate

NINR will display the OMB control number and expiration date in the upper right-hand corner of all data collection instruments. No waiver is being sought to display the expiration date for OMB approval.

## A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

NINR is in full compliance with the provisions contained within the Certification for Paperwork Reduction Act Submissions. No exceptions to the Certification for Paperwork Reduction Act Submissions are requested.

1. Assessed 5/24/2012. [↑](#footnote-ref-1)