CAPITAL CONSULTING CORPORATION

Feasibility Study To Conduct Process and Outcome Evaluations of the NHGRI Student Internship Program

Final Report

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Submitted to:

David Schneider
Chief
Acquisitions and Logistics Section
National Human Genome Research Institute
National Institutes of Health
Building 12A, Room 1025
12 South Drive
Bethesda, MD 20892

By:

Capital Consulting Corporation
Lynn M. Short, Ph.D., M.P.H.
Sumeet Kaur Atul
Barbara Singer

TABLE OF CONTENTS

Executive Summary

Program Background

The NIH Summer Internship Program (SIP) is an NIH-wide training program of at least 8 weeks during which students work individually with scientists in programs or labs from a variety of NIH Institutes or Centers (ICs). In addition to hands-on research experiences, interns sponsored by the National Human Genome Research Institute (NHGRI) participate in career development workshops and seminars sponsored by both NHGRI and the NIH Office of Intramural Training and Education (OITE).

Each year about 30% of the summer interns are in high school, 60% in college, and 10% in graduate, medical, or dental schools. Individual scientists select their own summer interns; there is no centralized selection process. In 2009 NHGRI sponsored 56 interns, at a cost of approximately $500,000.

Purpose/Objectives of the Study

The purpose of the study is to determine the feasibility of conducting process and outcome evaluations of the SIP sponsored by NHGRI. The evaluation is to cover three key areas: (1) the effectiveness of the SIP as a training program; (2) the effectiveness of OITE to increase diversity within the SIP, and (3) the personal, professional, and academic impacts of the SIP on its participants. Study results will be used to inform and improve the SIP.

Study Design and Methods

To understand the NHGRI SIP in sufficient detail to determine feasibility and develop the evaluation studies, CCC worked with the OITE staff to develop brief interview protocols/data collection forms for the OITE staff, research faculty members who have mentored SIP participants, and a selection of former interns. These stakeholders helped CCC identify relevant resources, program activities and outcomes, and methods for reaching process and outcome study participants.

Based on this preliminary information, CCC developed a logic model to clearly describe the program and ensure agreement among all key stakeholders. Using that model, CCC designed an evaluation plan that included:

- Specific study questions and measurable objectives to address goals for each evaluation component
- Key variables required to address objectives
- Evaluation study design
- Appropriate data sources and target audiences/participants for the process and outcome components
- Evaluation tools/survey instruments
- Power analyses to establish required sample sizes
- Data collection methods
- Statistical analysis plans
- Information for required Office of Management and Budget (OMB) and Institutional Review Board (IRB) clearance procedures

Key Findings/Results

The *process evaluation* will determine the extent to which the program is operating as intended. It will include interviews with SIP mentors and interns, an intern log, and surveys of OITE staff members, mentors, and interns.

The *outcome evaluation* will assess the degree to which interns learned about biomedical sciences, pursued contact and networking opportunities, and committed to and achieved education and careers in the biomedical sciences. In addition, the study will examine differences in these outcomes based on specific program and/or student characteristics and will identify factors contributing to these outcomes.

In addition to determining the extent to which program goals have been achieved, the study will examine differences in interns' levels of commitment and achievement in attaining education and careers in biomedical fields, based on specific program and/or student characteristics, and will identify factors contributing to interns' levels of commitment and achievement in attaining education and careers in biomedical fields. The evaluation is to be a 3-year prospective study, with data collected at the beginning and end of the internship period, as well as annually beginning the following April, when students will know their upcoming schedule.

Power calculations for the designed study specify a sample of 150 new interns with an anticipated attrition rate of 20%. Given the modest size of the NHGRI SIP, the study will require either four waves of NHGRI SIP participants from consecutive summers OR one wave of interns from multiple ICs. NHGRI anticipates interest from several ICs and is planning to enlist their participation in what is now envisioned as a pilot for a full study of all NIH interns.

Conclusions/Recommendations/Future Directions

Given the decision to include additional ICs in the study, with a focus on piloting a broader evaluation of the full NIH SIP, the specific objectives and instruments that have been developed will need careful scrutiny and some alteration to ensure relevance for all participants. Prior to implementation, the evaluation plan and instruments will need the approval and support of the overarching NIH OITE as well as representatives from participating ICs.

Introduction

The Summer Internship Program (SIP) is a very competitive NIH-wide training program formalized in 1991, which is currently administered by the NIH Office of Intramural Training and Education (OITE) and provides interns the opportunity to work side-by-side with leading scientists. The NHGRI SIP is housed in the Institute's Intramural Training Office (ITO). At NHGRI, students receive stipends commensurate with their academic levels, and NHGRI investigators provide financial support for the interns within the investigators' groups. Students are required to work at least 8 weeks in an NHGRI lab or research group and participate in NHGRI-sponsored career development workshops and seminars. They also are encouraged to participate in OITE-sponsored career development workshops and seminars.

Each year about 30% of summer interns are in high school, 60% are in college, and 10% are in graduate, medical, or dental schools. Individual scientists select their own summer interns; there is no centralized selection process. In 2009 NHGRI sponsored 56 interns, at a cost of approximately $500,000.

The NHGRI's ITO is the focal point for training at NHGRI, while contributing to the diverse pipeline of individuals trained in genetics and genomics. Program goals for SIP include:

I. Short-Term Goals
   a. Expose interns to topics in the biomedical sciences
   b. Expose interns to research experiences
   c. Increase student understanding of concepts in the biomedical sciences
   d. Increase the number of participants from diverse backgrounds, including individuals traditionally underrepresented in the biomedical sciences
   e. Increase student awareness of career opportunities in biomedical fields

II. Intermediate Goals
   a. Provide opportunities for interns to gather resources and contacts to transition to the next career phase
   b. Increase the self-confidence and ability of interns to identify themselves as capable of pursuing a career in a biomedical or related field
   c. Increase diversity in the academic pipeline in biomedical fields
   d. Encourage retention in biomedical fields of study

III. Long-Term Goals
   a. Sustain interest in biomedical-related fields throughout academic career (completing degrees in biomedical sciences)
   b. Increase the number of individuals who pursue careers in the biomedical sciences
   c. Increase the number of individuals from underrepresented groups (URGs) who pursue careers in the biomedical sciences

Purpose and Objectives of the Feasibility Study

The purpose of the feasibility study was to determine the feasibility of conducting process and outcome evaluations of the SIP sponsored by NHGRI. The evaluation is to cover three key areas:

- Effectiveness of SIP as a training program
- Effectiveness of ITO to increase diversity within SIP
- Personal, professional, and academic impacts of SIP on its participants

NHGRI sought contractor support to complete the following tasks:

- Assess summer program goals and inputs
- Refine key feasibility study questions
- Identify and assess data sources
- Conduct key stakeholder interviews (e.g., ITO Training Director, ITO Program Coordinator, ITO staff)
- Meet with ITO to discuss findings from interviews
- Write and submit a midpoint progress report
- Develop data collection tools (i.e., appropriate mechanisms to collect data for program evaluation)
- Provide guidance to ITO to conduct a pretest of the data collection tools
- Write and submit final report that includes executive summary
- Communicate weekly (by phone or in person) with the ITO contracting officer technical representative and/or the ITO staff

Capital Consulting Corporation's (CCC) process for completing these tasks is presented below.

Technical Approach

Task 1 – Project Management

Task 1.1: Opening Meeting

The CCC project director, evaluation specialist, and research assistant met with the NHGRI ITO staff upon award of the contract in September 2010 to introduce the project staff and to discuss the tasks to be accomplished, NHGRI's expectations for the project, the project management plan, and the delivery products and dates outlined in the solicitation. CCC prepared a meeting agenda, project overview, and draft timeline for distribution at this meeting.

Task 1.2: Project Management

At the opening meeting, CCC presented a draft Project Management Plan, including an outline of specific tasks, approaches, staffing, and management responsibilities of the project team; allocation of personnel for the project; and a description of CCC's assumptions. The Project Management Plan also included a timeline outlining start dates, completion dates, and milestones for completing the project task activities (summarized in the report included in Attachment A). Almost all activities and milestones were completed on schedule.

Task 1.3: Reports

CCC developed a midpoint progress report which was due by October 15, 2010, although the project had just begun at that time. The report (see Attachment A) described tasks to be accomplished, tasks completed, issues that might delay future progress, and strategies proposed to address stated issues. Throughout the project, CCC submitted to the NHGRI Project Officer weekly updates of tasks accomplished, and draft materials for review and feedback. Two conference calls were held with several key ITO stakeholders on February 3 and March 17, 2011, to present a summary of the project to date and to discuss questions and issues in need of resolution. This final report and executive summary have been checked to ensure 508-compliance.

Task 1.4: Deliverables

In addition to the reports described above, CCC developed the following deliverables:

- Preliminary questions for the ITO staff and a selection of SIP mentors and interns to gain a clear understanding of the SIP
- A logic model describing the SIP
- An evaluation plan and study design in alignment with NHGRI's program goals
- Evaluation tools, including an intern log and surveys for interns, mentors, and the ITO staff
- A list of resources and contacts needed to follow necessary IRB and OMB clearance protocols

Task 2 – Development of Evaluation Plan

To understand the NHGRI SIP in sufficient detail to determine feasibility and develop the evaluations, CCC initially reviewed the NHGRI Web site and the online NIH student intern application. The CCC team also requested pertinent documents or materials that could help orient the team to the program. Also, the team had an informative discussion with key ITO stakeholders at the introductory meeting, as well as several subsequent discussions with the Project Officer. CCC also conducted an Internet search to locate other student intern evaluations; finding nothing similar to this intended project, the CCC team spoke with a few U.S. Centers for Disease Control and Prevention (CDC) staff members who had been involved with CDC internship programs. They expressed frustration that they also had found nothing in their searches for evaluations of internship programs.

To help CCC better understand the program and identify relevant program activities and available resources (e.g., human capital, archival data), the team developed interview protocols for key ITO stakeholders and a selection of SIP mentors and students. The stakeholders helped CCC understand intern experiences and determine methods for contacting process and outcome study participants (i.e., SIP mentors and interns). Interview protocols and a brief summary of information received from mentors and students are provided in Attachments B through E. During the entire 6-month Phase 1 development process, CCC was fortunate to maintain open lines of communication with the Project Officer and a few key stakeholders to address questions and resolve issues.

Once CCC had received information from ITO, several SIP mentors, and a selection of former students, the team developed a logic model, with feedback from ITO, to clearly describe the program and ensure agreement among all key stakeholders. The Logic Model is provided in Attachment F.

CCC then developed the evaluation plan and study design. The team worked closely with the ITO staff to ensure that the plan and design would meet the staff's needs and interests. The plan, provided in Attachment G, delineates:

- Specific study questions and measurable objectives to address goals for each evaluation component
- Key variables required to address objectives
- Evaluation study design
- Appropriate data sources and target audiences/participants for the process and outcome components
- Power analyses to establish required sample sizes
- Data collection methods
- Statistical analysis plans

Once the draft plan was developed, CCC began work on developing the evaluation instruments. To best understand how interns spend their time during the internships, the team developed a log, which interns will complete online at the end of each week, after keeping daily track of their activities in personal journals. CCC also developed a survey to collect both process and outcome data from interns, which they will complete at the beginning and end of their internships. In addition, three followup surveys will be administered annually to interns, which will focus primarily on their educational and career intentions and achievements. Moreover, surveys were developed for SIP mentors and ITO staff members to complete the process evaluation. Additionally, interviews are planned with a sample of mentors and interns to provide more indepth information.

For this Phase 1 study, CCC worked with the ITO staff to ensure that data collection tools are capturing the required information and revised instruments according to feedback and suggestions. The intern log and instruments are provided in Attachments H through K.

The NHGRI ITO staff has decided to include another one or two NIH ICs to increase the size of the intern pool, allowing the study to be conducted in one wave rather than in several waves. Therefore, the instruments may need slight revisions to accommodate the needs of those ICs and will be pilot-tested once those instruments have been finalized.

CCC also developed a list of resources and contacts needed to follow the necessary OMB and IRB clearance protocols. This document is provided in Attachment L.

Staffing

The following paragraphs describe the roles and responsibilities of CCC staff members show are participating in the project.

Project Director, Barbara Singer: Ms. Singer was the CCC project manager, who supervised project staff, ensured that tasks were accomplished within the required timeframes, and managed the budget. She also ensured that reports were delivered on time, and participated on weekly conference calls with the ITO Project Officer and additional calls with ITO stakeholders.

Management Consultant IV (Evaluation Specialist), Lynn M. Short, Ph.D., M.P.H.: Dr. Short was the key staff members on the project, providing support to the following tasks:

- Assessing summer program goals and input
- Refining key feasibility study questions
- Identifying and assessing data sources
- Developing interview protocols and conducting key stakeholder interviews (i.e., ITO Training Director, ITO Program Coordinator, ITO staff members, and selected SIP mentors and former interns)
- Meeting with ITO to discuss findings from interviews
- Writing the midpoint progress report
- Developing the logic model, evaluation plan, and data collection tools (i.e., appropriate mechanism to collect data for program evaluation)
- Identifying requirements for IRB and OMB clearance procedures
- Providing guidance to ITO
- Writing the final report and executive summary
- Communicating weekly (by phone or in person) with the ITO Project Officer and/or ITO staff

Policy Analyst II (Research Assistant), Sumeet Atul: Ms. Atul assisted Dr. Short, the evaluation specialist, with the above tasks upon request. She took the lead for developing the IRB/OMB clearance procedure document, participated in all conference calls and meetings, and developed summary reports for each of our weekly and special conference calls. She also reviewed all instruments to ensure coverage of all objectives delineated in the evaluation plan.

Scientific Editor II, Donna Cay Tharpe: Ms. Tharpe ensured the quality of the mid-point and final reports. She worked with the desktop publisher to prepare the reports, especially the final report.

Publications Production Staff, Char Glendening: Ms. Glendening, our desktop publisher, provided formatting for the mid-point and final reports.

Attachment A: Midyear Progress Report

FEASIBILITY STUDY TO CONDUCT PROCESS AND OUTCOME EVALUATIONS OF THE NHGRI SUMMER INTERNSHIP PROGRAM

You must submit an Evaluation Office (EO) status report form by Close of Business on October 15 to evaluate@mail.nih.gov for every year your project is ongoing. This requirement also includes submitting a final status report form when the project and final report are completed.

EO Reference Number: 10-1009 NHGRI

Project Title: Feasibility Study To Conduct Process and Outcome Evaluations of the NHGRI Summer Internship Program

Project Officer: *Please provide contact information for all Project Officers, if multiple.*
Name: Carla L. Easter, Ph.D.; Science Education Specialist
Institute or Center: National Human Genome Research Institute
Office Address: Building 31, Room B1-B55, MSC 2070, 31 Center Drive, Bethesda, MD 20892
Telephone Number: (301) 594-1364, Fax: (301) 480-5008
E-mail Address: easterc@mail.nih.gov

Performer/Contractor: *Please provide information for all project contractors, if multiple.*
Name: Capital Consulting Corporation
City and State: Rockville, MD 20852
Type of Procurement: GSA MOBIS, T&M
Contracting Office/Officer: David Schneider

Project Implementation: *Please briefly describe how the project has progressed, including any changes to the original project implementation plan.*

Brief Overview
To understand the NHGRI SIP in sufficient detail to determine feasibility and develop the evaluation studies, CCC worked with the NHGRI ITO staff to develop brief interview protocols/data collection forms for the ITO staff, research faculty members who have mentored SIP participants, and a selection of former interns. These stakeholders are helping CCC identify relevant program activities and outcomes, as well as available resources, such as those specified in the solicitation (human capital, funding, archival data). Additionally, information obtained from the stakeholders is helping CCC determine methods to be included in the study design for contacting process and outcome study participants (i.e., NIH IC mentors and SIP students).

The project has been proceeding according to the timeline provided below. Specific accomplishments include:

1. A list of stakeholder contacts was developed and distributed by NHGRI on September 16, 2010.
2. Draft questions for ITO staff members, mentors, and students was sent to the team on September 16, 2010.
3. Questions were updated and refined based on feedback from the NHGRI staff by September 23, 2010.
4. Questions for the ITO staff were sent to specified contacts on September 23, 2010.
    - Discussion with ITO contact to discuss questions on 9/28. Contact will complete form based on this discussion.

5. Questions were sent to mentors on September 21, 2010, and to students on September 23, 2010.
6. Relevant SIP reference documents were received from NHGRI ITO on October, 13, 2010.
7. Responses have been received to date (10/14/10) from:
    - 10 of 14 Mentors: 2 phone interviews, 8 written responses
    - 4 of 9 Students: 1 phone interview, 3 written responses

Successes and Challenges

The relationship between CCC and the NHGRI ITO staff has been collegial and collaborative, which has facilitated progress during the initial stage of the project. Also, the mentoring researchers CCC has contacted have been forthcoming and helpful in providing valuable information through their feedback to the questions sent to them by CCC. To date, however, CCC have received less feedback than anticipated from prior students; there is a need to determine better strategies for contacting them.

Timeline and Benchmarks

Deliverable/Milestone/Task	Timeframe
	2010
Project Orientation:	
- Introductory meeting with ITO contact, introduction of key stakeholders - Receive/review project-related documents	9/13 9/13-20
Develop interview protocol for key stakeholders to determine feasibility, parameters, logistics	9/24
Make appointments with key stakeholders for interviews	9/24-10/8
Interview key stakeholders (ITO staff members, IC mentors, possibly past SIP students)	9/24-10/27 (ongoing)
Subsequent e-mail/phone contacts with key stakeholders, for addressing questions, etc.	As needed
Develop logic model and deliver to Project Officer: - e-mail to ITO stakeholders - discuss via conference call	10/29 11/3 11/10
Update logic model	11/12
Develop draft study design/questions/measurable objectives/key variables: - Deliver to Project Officer - e-mail to key contacts/receive feedback/update accordingly	 11/18 11/20
Midpoint Progress Report, including deliverable outlining study design, key variables, and study questions in alignment with program goals. Deliver to Project Officer.	12/10
	2011
Develop evaluation instruments for process and outcome evaluations: - Deliver to Project Officer - e-mail to key contacts/receive feedback/update accordingly	 1/14 1/18
Work with ITO staff to pilot-test draft evaluation instruments	1/14
Finalize deliverable describing required evaluation tools, data sources, statistical analyses, and data collection plans. Send to Project Officer and ITO stakeholders.	1/28

Deliverable/Milestone/Task	Timeframe
Hold conference call to discuss evaluation plan	2/4
Update evaluation plan as needed	2/10
Develop final evaluation tools based on pilot-test results and deliver to Project Officer	2/15
Contact NIH OMB and IRB to determine clearance needs based on planned evaluation studies	2/15
Develop deliverable listing resources and contacts needed to follow necessary clearance procedures	2/28
Finalize Feasibility Study Report and Executive Summary and deliver to Project Officer	3/15
Meet at appropriate NIH office(s) to present results	3/31
Hold weekly calls with Project Officer to discuss project	

Funds Used to Date
The total cost through 9/30/10 is $5,719.50.

Status of Ongoing Project
Actual Start Date: 9/13/10
Actual Completion Date: 3/31/11

Status of Completed Project (including final report). *Please send the final report document or Web site address to the EO at evaluate@mail.nih.gov.*

Actual Start Date: 9/13/10
Actual Completion Date: 3/31/10
Final Report Title: Feasibility Study To Conduct Process and Outcome Evaluations of the NHGRI Summer Internship Program: Final Report
Final Report Abstract. *Please address the five sections below, limit to a maximum of 500 words, and use plain language.*

- Purpose of Study:
- Program Background:
- Methods:
- Findings/Results:
- Recommendations/Future Steps:

Attachment B: Preliminary Interview Protocol – NHGRI ITO SIP Organization Staff

FEASIBILITY STUDY TO CONDUCT PROCESS AND OUTCOME EVALUATIONS OF THE NHGRI SUMMER INTERNSHIP PROGRAM

1. How are students selected into the program?
   a. What proportion of students is specifically selected by a researcher who already knows them? (Is this knowledge from a prior year's participation in the SIP?)
2. What is the specific breakdown in education levels of SIP participants over the past two summers? (i.e., number of college undergraduates, college graduates, high school students, etc.)
3. What prior or related programs have SIP participants been involved with (e.g., Howard Hughes Medical Institute, Cloisters program – what is the nature of these programs?)
4. What is the range in length of internship (i.e., 8 weeks minimum to maximum)? What is the average length?
5. Do any students ever drop out? If so, why? Who is dropping out (what are the characteristics of the drop-outs)?
6. What proportion of the 50 NHGRI researchers participate in the SIP?
7. What are the specific program activities and additional opportunities for all SIP participants regardless of their specific assignment?
   a. How are the program activities chosen?
   b. Is there a method for determining the effectiveness of these programs?
8. What would you suggest as appropriate performance measures for the SIP program?
9. What different types of programs do students participate in for their internship? e.g., research labs, behavioral sciences were mentioned as two primary distinctions. Are there others we should include in the evaluation in some capacity?
10. How many interns does each mentor have (what is the minimum, maximum, and average over the past 2 years)? Do most have one, and a few have more, or does it vary?
11. What are the specific characteristics of students from traditionally URGs?
    a. Is their funding through a separate program?
    b. How do we identify this group for the evaluation?
12. How are the funds for the SIP program distributed (i.e., student stipends, special programs, lab materials, etc)?
13. Is there an electronic database of exit surveys we can analyze now to help us prepare the evaluation design?
14. What additional information would help us understand the student intern program better?

Attachment C: Preliminary Interview Protocol – IC Researchers/SIP Mentors

FEASIBILITY STUDY TO CONDUCT PROCESS AND OUTCOME EVALUATIONS OF THE NHGRI SUMMER INTERNSHIP PROGRAM

Initial Questions – IC Researchers/SIP Mentors

The NHGRI ITO has contracted with Capital Consulting Corporation to study the feasibility of evaluating the NHGRI Summer Internship Program (SIP) and develop an evaluation plan. We have selected you as a valued SIP mentor to help guide our understanding of the program. Additional input is being sought from the ITO staff and a selection of former student participants.

Your responses to the following questions will help guide us in developing a meaningful and useful evaluation.

Please address the following questions, based first on your own experiences and then on the experiences of other NHGRI researchers participating in this program.

1. How many summer interns have you mentored? ___ Over how many years? ___
2. How many mentors and other researchers does each intern typically interact with during their summer project?
3. Do you mentor the students directly, or does someone in your lab mentor the students?
4. How do you select your students? What characteristics do you look for?
5. What is the nature of the student involvement in your research program?
6. What specific lab activities are the student interns engaged in for their summer project? What do you try to teach the students who work in your lab?

a. What additional opportunities do you provide to students relative to their specific project?

7. What assessment or performance measures are in place for SIP participants relative to their summer project?

a. Are there assessment mechanisms for everyone working in the lab? If so, how do summer interns perform relative to other trainees?

8. What do students really get out of the program?
9. What do the mentors get out of the program?
10. What proportion of the summer interns return to NIH for future summers or longer term training programs (e.g., postbaccalaureate, graduate school, etc)?
    a. How many/what proportion go on to a longer term training program elsewhere?
11. For what proportion of your interns have you written recommendation letters?
12. What proportion of your interns have you stayed in touch with after the summer program?

Attachment D: Preliminary Interview Protocol – Past SIP Interns

FEASIBILITY STUDY TO CONDUCT PROCESS AND OUTCOME EVALUATIONS OF THE NHGRI SUMMER INTERNSHIP PROGRAM

Initial Questions – Past SIP Interns

The NHGRI ITO has contracted with Capital Consulting Corporation to develop an evaluation study of the NHGRI Summer Internship Program (SIP). We have selected you as a valued SIP participant to help guide our understanding of the program. Additional input is being sought from the ITO staff and some of the researchers who have served as mentors in the program.

Your responses to the following questions will help guide us in developing a meaningful and useful evaluation.

Please address the following questions based first on your own experiences and then on your knowledge of the experiences of other student interns participating in this program.

1. In what year did you first participate in the Summer Internship Program? Summer of _____.
2. How did you originally learn about the SIP?
3. Why did you decide to apply for the SIP?
4. How does participation in the NHGRI SIP affect most students? For example, does the program lead to a change in majors or career plans or perceptions about what research is and one's ability to do research? (What was your experience? What about other students you know?)
5. How do students' interests in genetics/genomics and biomedical science (or science in general) change when they participate in the NHGRI internship program?
6. To what extent do students take advantage of the various opportunities that are available during their internships?
    a. Do students find the additional opportunities helpful?
7. What do students get out of the program?
8. What kinds of things do the students like about the program?
9. What kinds of things do the students *not* like about the program?
10. To what extent do students stay in touch with their mentors after the internship?
11. To what extent do students stay in touch with one another after the internship?
12. What additional information would help us understand the program better?
    a. About how many past interns could we locate through you for a retrospective evaluation study?
13. How do your expectations for summer interns differ from other trainees?
14. What additional information would help us understand the SIP better?

Attachment E: Preliminary Interview Summary – SIP Mentors and Interns

FEASIBILITY STUDY TO CONDUCT PROCESS AND OUTCOME EVALUATIONS OF THE NHGRI SUMMER INTERNSHIP PROGRAM

Initial Input Regarding SIP – Mentors and Interns

At the outset of the feasibility study, a feedback form was developed for NHGRI ITO staff, faculty mentors, and student interns to better understand the nature of the SIP. One ITO staff member provided information through a phone interview and followup written response at the end of September, 2010. Ten of the fourteen mentors asked to respond did so, with eight providing written responses and two participating in phone interviews between September 20 and October 4, 2010. Of the nine interns asked to provide information, only four responded, with one providing a phone interview and the remaining three submitting completed forms between September 27 and October 13, 2010.

Mentors were asked about the number of interns they had worked with, the characteristics of students they preferred, their intern selection methods, the nature of student involvement in their program, specific activities required/requested of interns, their expectations of intern performance, and any assessment methods they used with their students. They also were asked what they as well as their students actually got out of the program, the proportion of students for whom they had written recommendation letters, their ongoing contact with former interns, and for any additional information that would be helpful.

Students were asked how they learned about the SIP, when and why they applied, how the program affects interns in general and how it affected them in particular, whether they took advantage of and found helpful the additional opportunities they were offered, things they liked/disliked about the program, what they really got out of the program, whether they stayed in touch with their mentors or other interns, and for any additional information that would be helpful.

Key findings indicate that students' experiences vary considerably, with a fairly wide variety of tasks and activities. They often are mentored by postdoctoral researchers or graduate students in the lab in addition to the NHGRI faculty. Although several mentors take interns to provide learning opportunities to the students and mentoring opportunities to their staffs, others seem more interested in obtaining help in managing their workload. Some interns are encouraged to think creatively, whereas others are taught rote skills. Some interns are encouraged or expected to participate in meetings and presentations. All seem to be provided a significant amount of individual instruction and attention. Although none of the mentors assessed their interns' performance, all mentors felt their interns benefited from the program. Additionally, all mentors believed the interns were a benefit to their programs and they were enthusiastic about the SIP.

The four students who responded were all quite grateful for the opportunities they were provided. They recognized that they were exposed to many things they would not have experienced elsewhere, obtained skills they would use long into the future, and made connections that would help them progress in their education and career. One student reported that the experience "cemented my career decisions, and for others it gave them other options."

Interns found that most additional opportunities were valuable, especially those concerning career opportunities. However, interns sometimes found that these opportunities interfered with work in the lab, found some "not really useful," or reported too many events, especially those close to the poster project.

One key finding indicated the importance of the experience in clarifying career goals but not specifically toward conducting genetics/genomics research. Although the experience increased interest in biomedical science for some, one student noted that "I enjoyed everything—learning, research—but after that, I really

know it's not the career path for me. Now I want to get a master's degree in a field in which I help people understand the sciences." It helped another student realize he wanted to go to medical school and specialize in the field of dermatology.

The interns recognized the effect the program had on them. One reported that the program "made me want to grow, and not want to stop. It made me realize how important education is to me." One said: "I thoroughly enjoyed working at NIH, not only because of the research, but also because I felt welcomed and respected by the people I worked with." All were very happy they had participated in the program.

Attachment F: Logic Model

FEASIBILITY STUDY TO CONDUCT PROCESS AND OUTCOME EVALUATIONS OF THE NHGRI SUMMER INTERNSHIP PROGRAM

AGENCY: NIH NHGRI ITO	**STRATEGY:** PROVIDE NHGRI SUMMER INTERNS OPPORTUNITIES TO WORK WITH WORLD-CLASS BIOMEDICAL RESEARCHERS
Project Goal: Contribute to the diverse pipeline of individuals trained in genetics and genomics	**Target Population**: High School, College, and Graduate Students

HOW DOES YOUR PROGRAM PROVIDE SERVICE?		**HOW MUCH SERVICE DO YOU PROVIDE?**	**WHAT DIFFERENCE DOES THIS PROGRAM MAKE?**		
INPUTS **What RESOURCES are dedicated to this program?**	**ACTIVITIES** **What SERVICES are provided?**	**OUTPUTS** **What AMOUNTS OF SERVICE are provided?**	**OUTCOMES** **What are the BENEFITS TO PROGRAM PARTICIPANTS?** (SIP participants are referred to as "students" below.)		
			Short-Term Outcomes	Intermediate Outcomes	Long-Term Outcomes
- NIH Internship Application Process - Recruitment efforts – ITO staff and faculty - ITO Staff time - Research faculty and staff time - Lab/other facilities - Lab/other equipment - Student stipends - ITO relationships with other NIH offices, faculty, PSS, OIM, police, OITE - Relationships with local schools and collaborating programs	- Individualized summer training for interns - Hands-on experience - NHGRI-sponsored career development workshops, seminars, and events - OITE-sponsored career development workshops, seminars, and events - Opportunity to present research to NHGRI and NIH community; two scientific poster presentations - Ongoing relationships with mentors - Letters of recommendation	- ~ 50 SIP participants annually - Minimum 8 weeks of training provided per student - 1 mandatory NHGRI SIP orientation - 5 mandatory NHGRI-sponsored workshops/ seminars/events - 25 optional OITE-sponsored workshops/ seminars/events - Student opportunities to gather resources and contacts to transition to next career phase	- Students are exposed to genetics and genomics topics. - Students gain research experience. - Students gain understanding of concepts in genetics and genomics. - Students gain awareness of career opportunities in biomedical fields. - There are increasing numbers of participants from diverse backgrounds, including individuals who from traditionally underrepresented groups (URGs) in the biomedical sciences.	- Students use resources and contacts provided during internship to transition to next career phase. - Students are confident and able to identify themselves as capable of pursuing a career in a biomedical or related field. - Students plan to pursue biomedical fields of study. - Students from traditionally URGs plan to pursue education and careers in biomedical fields, particularly genetics and genomics. - Students apply to and go on to other programs in genetics or genomics (or return to NHGRI).	- Students sustain their interest in biomedical-related fields throughout their academic career, completing degrees in biomedical sciences, particularly in genetics and genomics. - Students pursue careers in biomedical sciences, particularly in genetics and genomics. - Students from traditionally URGs pursue careers in biomedical sciences, particularly in genetics and genomics.

Attachment G: Evaluation Plan

FEASIBILITY STUDY TO CONDUCT PROCESS AND OUTCOME EVALUATIONS OF THE NHGRI SUMMER INTERNSHIP PROGRAM

Evaluation Plan

The mission of the National Human Genome Research Institute's (NHGRI) Intramural Training Office (ITO) is to serve as a focal point for training at NHGRI, while contributing to the diverse pipeline of individuals trained in the biomedical sciences. ITO's program goals for the Summer Internship Program (SIP) are listed below:

I. Short-Term Goals
   a. Expose interns to topics in the biomedical sciences
   b. Expose interns to research experiences
   c. Increase student understanding of concepts in the biomedical sciences
   d. Increase the number of participants from diverse backgrounds, including individuals from traditionally URGs in the biomedical sciences
   e. Increase student awareness of career opportunities in biomedical fields

II. Intermediate Goals
   a. Provide opportunities for interns to gather resources and contacts to transition to the next career phase[1]
   b. Increase interns' self-confidence and ability to identify themselves as capable of pursuing a career in a biomedical or related field
   c. Increase diversity in the academic pipeline in biomedical fields
   d. Encourage retention in biomedical fields of study

III. Long-Term Goals
   a. Sustained interest in biomedical-related fields throughout academic career (completing degrees in biomedical sciences)
   b. Increase the number of individuals who pursue careers in the biomedical sciences
   c. Increase the number of individuals from URGs who pursue careers in the biomedical sciences

[1] As stated, this is a short-term, process-related goal. The outcome goal is that interns actually gather those resources and contacts.

Selected Demographic Characteristics of Former NHGRI SIP Interns

NHGRI SIP by Education Level at Time of Application:

	2009	2008
HS Junior:	11%	21%
HS Senior:	11%	10%
College Freshman:	20%	18%
College Sophomore:	18%	14%
College Junior:	28%	21%
College Senior:	5%	6%
Graduate Student:	7%	2%
Medical Student:	0%	8%

	2009 -- 2008
URG	3.9% (n=19) – 25.5% (n=13)
Non-URG	66.1% (n=37) – 74.5% (n=38)

Purpose

The purpose of the evaluation study is to determine (1) the effectiveness of SIP as a training program; (2) the effectiveness of NHGRI's ITO to increase diversity within the SIP, and (3) the personal, professional, and academic impacts of the SIP on its participants.

The effectiveness of the SIP as a training program shall be determined by both programmatic and personal factors. Programmatic factors include the extent to which interns are exposed to biomedical topics, are provided with research experiences, and are provided with opportunities to gather resources and contacts in genetics/genomics. Personal factors include interns' understanding of genetics/genomics concepts, awareness of career opportunities in biomedical fields, and self-confidence and ability to identify themselves as capable of pursuing a career in a biomedical field.

The effectiveness of ITO to increase diversity within the SIP shall be determined by the proportion of participants from traditionally URGs participating in the SIP as well as in maintaining interest and continuing to pursue education and careers in biomedical fields.

The personal, professional, and academic impacts of the SIP on its participants shall be determined in the short term by interns' level of commitment to attain education and careers in biomedical fields and in the longer term by sustained interest as well as actual attainment of such education and/or careers.

Study results will be used to inform and improve the SIP.

Objectives

1. Determine the extent to which the program goals described above have been achieved
2. Determine differences in interns' levels of commitment/achievement in attaining education and careers in biomedical fields based on specific program and/or student characteristics
3. Determine factors contributing to interns' levels of commitment/achievement in attaining education and careers in biomedical fields

Evaluation Questions

Demographic Information[2]

- Age, sex, level of education, URG
- Amount and type (lab versus other) of prior research experience

Additional Background Questions

- Prior relationship with NHGRI faculty
- Motivation for applying to the program
- Incoming intentions/commitment to biomedical fields
- Intern's home location (local/more distant)

Process Evaluation Questions

1. What proportion of SIP participants[3] are from diverse backgrounds, including individuals traditionally underrepresented (members of URGs) in the biomedical sciences?
2. To what extent are interns:
   a. Exposed to biomedical topics?
   b. Provided opportunities to conduct research?
   c. Given their own research project or project component?
   d. Provided information concerning career opportunities in biomedical fields?
3. To what extent do interns:
   a. Attend mandatory and optional workshops, seminars, and events sponsored by NHGRI and OITE?
   b. Receive resources and contacts to transition to the next career phase?
   c. Maintain ongoing relationships with their mentors?
4. How much time do interns spend (and how interested are they) in various activities, including independent research in the lab, interviewing patients, working with/learning from their mentors, attending various functions (presenting at/attending journal clubs; attending seminars), reading scientific literature, networking with peers, networking with mentor(s) (official, and ad hoc), keeping records, working in wet lab, designing experiments, analyzing data, preparing communications (i.e., posters, papers) (Also: how much career counseling, mentoring do they receive? Do they find good role-models?)
5. How satisfied are interns and mentors with the program? What specific experiences made the program good/bad? What suggestions do participants (interns and mentors) have for improvement?
6. How satisfied are mentors with:
   a. their mentoring experience, and
   b. the competence of the help they received from the interns?

[2] Due to its complexity, URG status will be obtained from ITO rather than directly from student survey. Demographic and background information will be used in descriptive, comparative, and predictive analyses.

[3] Also referred to as "interns"

Outcome Evaluation Questions

NOTE: Prefollowup/postfollowup surveys will contain many of these concepts for comparison over time, with followup surveys focusing primarily on commitment and attainment of education and career goals.

Short-Term and Intermediate Questions (immediately and 6 months following internship):

1. To what extent do interns:
   a. Gain understanding of concepts in the biomedical sciences?
   b. Gain awareness of career opportunities in biomedical fields?
   c. Gather resources and contacts to transition to the next career phase?
   d. Receive letters of recommendation from their mentors?
2. Following their participation in the SIP, how confident and able are interns to identify themselves as capable of pursuing a career in a biomedical or related field?
3. To what extent did the internship help clarify interns' interests in biomedical fields of study?
4. How committed are interns to attaining education and careers in biomedical fields?
5. To what extent do interns use the resources and contacts received during internship to transition to the next career phase?
6. What proportion of interns (including those from URGs) plan to pursue education and careers in biomedical fields of study?
7. What proportion of interns apply to and go on to other programs in the biomedical field or return to NHGRI (include relevant questions for different levels of interns' levels of education)?
8. What factors (including all items described above as well as demographic information such as education level and prior research experience) contribute to SIP participants' plans to pursue education and careers in biomedical fields?

Long-Term Evaluation Questions:

1. To what extent do interns sustain their interest in biomedical-related fields throughout their academic careers (completing degrees in biomedical sciences)?
2. What proportion of interns pursue careers in the biomedical sciences?
3. What proportion of interns from URGs pursue careers in the biomedical sciences?
4. What factors contribute to SIP participants' attainment of education and careers in biomedical fields?

Comparative Evaluation Questions

Are there differences among SIP participants:

(a) Over time (preinternship, immediately postinternship, and 6 months and 1 year or more after internship)[4]?

(b) Between levels of prior research experience (no prior experience versus one or more research experiences prior to the SIP) and

(1) high school versus undergraduate education level? (NOTE: Insufficient numbers of high school interns with prior experience may preclude this analysis.)?

(2) members of URGs versus non-URGs? (Again, small sample sizes of URGs may preclude this analysis.)

[4] Problems with attrition may preclude long-term comparisons due to sample size requirements.

Are there differences among SIP participants:

(a) Over time (preinternship, immediately postinternship, and 6 months and 1 year or more after internship)?

(b) Between interns involved in wet-bench, dry-bench, and behavioral sciences research?

Outcomes of interest:

1. Level of confidence and ability to identify oneself as capable of pursuing a career in a biomedical science or related field
2. Level of commitment to attain education and careers in biomedical fields
3. Intermediate steps toward attainment of education and careers in biomedical fields (e.g., college major, application to graduate school in field, participation in internships or other training in biomedical field)
4. Actual attainment of education and careers in biomedical fields

Predictive Evaluation Questions

What factors lead to interns' commitment to attain and actual attainment of education and careers in biomedical fields?

Potential predictors include:

1. Intern's education level
2. Intern's URG status
3. Intern's parent/relative works at NIH
4. Intern has family member who is a biomedical professional
5. Level of intern's prior research experience
6. Level of intern's interest in pursuing a professional or graduate degree
7. Intern's parents' education
8. Perceived quality of intern's SIP experience
9. Perceived usefulness of enrichment activities
10. Perceived quality of the intern's mentoring experience
11. Amount of time intern spent in the lab
12. Intern is from (local) DC metropolitan area versus other geographical area

Evaluation Study Design

The process evaluation will include SIP participants, their mentors and lead faculty during the internship, and key ITO stakeholders. The outcome evaluation will focus exclusively on the SIP participants.

The outcome evaluation will be a prospective prepost and followup design with ongoing contact with SIP participants at 1-year intervals over a period of 3 years. Baseline data will be collected during intern orientation in May/June; postinternship data will be collected during a final event in August; and followup data will be collected in mid-April, when interns are likely to know their upcoming schedules for autumn but prior to final exams and summer activities.

The NHGRI ITO estimates it hosts 50 interns per year, with approximately 25% returning for a second or third summer. For consistency, this study will include and follow only first-time interns, yielding a pool of approximately 37 new interns per year.

To provide an adequate sample of 120 interns or more (see power calculations below), the study will require either four waves of NHGRI SIP participants from consecutive summers OR one wave of interns from NHGRI and one or two from additional NIH Institutes or Centers (ICs).

Considering the four-wave scenario involving only NHGRI interns, approximately 148 new interns would be recruited. Estimating 20% attrition over time would leave 118 interns for the study. Considering the study design chart below, data for this study would be collected for 6 years, beginning in May/June 2012, with the final data collection in April 2018.

Considering the scenario with a larger pool of interns from additional ICs, the study would require two waves, with 50 additional interns per year, or only one wave if 100 additional interns are included. Therefore, the study will run either 4 years in the two-wave scenario—from May/June 2012 through April 2016—or 3 years in the one-wave scenario—from May/June 2012 through April 2015. Dates are charted in the table below. If additional ICs are involved in the study, the evaluation questions and surveys will be reviewed with them and will be adjusted according to those ICs' needs and interests.

This study is considered a pilot for a full-scale evaluation of all 500 NIH interns, which would follow the Wave 1 pattern in the chart below at a later date. Given the same estimates of 25% returning interns and 20% attrition, this study would provide an estimated 300 interns, which would allow for more complex analyses (see power calculations below).

Additionally, a retrospective outcome study has been considered with a group of 150 former SIP participants. However, a method for locating an unbiased sample of prior interns has not been determined.

NHGRI SIP Evaluation Study Design Chart

MONTH		WAVE 1	WAVE 2	WAVE 3	WAVE 4
6/12		Pretest			
8/12		Posttest			
4/13		Followup 1			
6/13			Pretest		
8/13			Posttest		
4/14		Followup 2	Followup 1		
6/14				Pretest	
8/14				Posttest	
4/15		Followup 3	Followup 2	Followup 1	
6/15					Pretest
8/15					Posttest
4/16			Followup 3	Followup 2	Followup 1
4/17				Followup 3	Followup 2
4/18					Followup 3

Data Sources and Collection

Mentors, other faculty, and ITO stakeholders will receive evaluation forms immediately following the internship period. A selection of these three groups will be interviewed to collect more indepth information.

Interns will be asked to keep a personal journal, with weekly online entries, to log the time spent in various activities during the internship. Additionally, interns will receive evaluation forms immediately prior to and following the intervention, with an initial followup 8 months later and at two additional followups at 1-year intervals. To help maintain participation, followup surveys will be shorter than those completed baseline and postinternship, eliminating the respondent profile and most background questions. The second and third followup surveys also will eliminate questions related directly to the SIP experience and will focus primarily on education and career issues. To maintain connections with interns once they have left the program and help ensure their participation in the study, ITO intends to develop a Facebook page, Twitter account, or blog subscription with news and updates. If interns are trained to use this system early in the

internship and find it useful, they may be motivated to continue the relationship. It also may be possible to contact interns through their cell phone numbers, which may be kept through multiple transitions in other areas of their lives.

Near the end of their internships, interns will be visited in their labs to observe their work situation. Additionally, each intern will be asked to participate in a brief interview privately to discuss his or her experience. If an alternative design with interns from one or more additional ICs is adopted, a sample of interns from each participating division will be included in this component.

Although most intern information will be collected directly, URG status, a variable of primary importance to ITO, is not directly available. ITO determines interns' URG status by searching applicants' cover letters for representative keywords such as attendance at a Historically Black College or University, membership in the Hispanic Student Association, or membership in a historically African American fraternity or sorority. Therefore, NHGRI's URG status for each intern will be merged with the evaluation data base using matching variables, including first initials of first and last names, birth date, sex, education level, last four digits of the intern's social security number, and the NHGRI assignment branch.

If the long-term, retrospective study is conducted, participants will receive one evaluation form asking about their SIP experiences and later education and career decisions.

Analysis Plan

Descriptive statistics will be used to characterize interns and demonstrate the extent to which they achieve stated objectives. Multiple analysis of variance techniques will be used for comparative analyses. Multiple regression and possibly structural equation modeling techniques will be used for predictive analyses. Bias in followup data due to study dropouts will be determined by comparing baseline and immediate postinternship data for those who remain in the study versus those who drop out.

The design for comparing education level (high school versus undergraduate) and prior/no prior research experience over time is described in the following table:

2009 -- 2008		No Prior Research Experience	Prior Research Experience*
High School	22% (n=11) – 31% (n=16)		Sufficient sample size??
Undergraduate	71% (n=36) – 59% (n=30)		

The design for comparing URGs versus non-URGs and prior/no prior research experience over time is described in the table below:

2009 -- 2008		No Prior Research Experience	Prior Research Experience*
URG	3.9% (n=19) – 25.5% (n=13)		Sufficient sample size??
Non-URG	66.1% (n=37) – 74.5% (n=38)		

Power Calculations

Potential 3x2 Design

SIP Participants as Sampling Unit (Time factor is not displayed.)

	Little/No Prior Research Experience (No Lab)	Some/Much Prior Research Experience, Including Lab
Wet Bench		
Dry Bench		
Social/Behavioral		

Factor A in the table below represents Type of SIP Experience (Wet Bench, Dry Bench, Social/Behavioral). Factor B represents Prior Research Experience (None/Little, Some/Much). Using this design, with 162 cases (interns) distributed evenly among the cells (27 cases per cell), there is sufficient power to detect moderate differences in student outcomes.

Factor Name	Number of levels	Cases per level	Effect size f	Power
Factor A	Levels= 3	54	0.25	0.80
Factor B	Levels= 2	81	0.25	0.88
Interaction AB	df= 2		0.25	0.80

Within cell SD= 1.00, Variance= 1.00
Cases per cell= 27, Total N of cases= 162
Alpha (2-tailed)= 0.05

Power computations: Non-central F

2x2 Design

SIP Participants as Sampling Unit (Time factor is not displayed.)

	Little/No Prior Research Experience (No Lab)	Some/Much Prior Research Experience, Including Lab
High School		
College Undergraduate		

Factor A in the table below represents Education Level (high school versus college undergraduate). Factor B represents Prior Research Experience (None/Little, Some/Much). Using this design, with 128 cases (interns) distributed evenly among the cells (32 cases per cell), there is sufficient power to detect moderate differences in student outcomes.

Factor Name	Number of levels	Cases per level	Effect size f	Power
Factor A	Levels= 2	64	0.25	0.80
Factor B	Levels= 2	64	0.25	0.80
Interaction AB	df= 1		0.25	0.80

Within cell SD= 1.00, Variance= 1.00
Cases per cell= 32, Total N of cases= 128
Alpha (2-tailed)= 0.05

Power computations: Non-central F

One Between-Subjects Factor

SIP Participants as Sampling Unit:

	Baseline	Immediate Postintervention	8-Month Followup
Wet Bench			
Dry Bench			
Social/Behavioral			

Factor A in the table below represents Type of SIP Experience (Wet Bench, Dry Bench, Social/Behavioral). Using this design, with 150 cases (interns) distributed evenly among the cells (50 cases per cell), there is sufficient power to detect moderate differences in student outcomes.

Factor Name	Number of levels	Cases per level	Effect size f	Power
Factor A	Levels= 3	50	0.25	0.78

Within cell SD= 1.00, Variance= 1.00
Cases per cell= 50, Total N of cases= 150
Alpha (2-tailed)= 0.05

Power computations: Non-central F

Multiple Regression

These analyses will be conducted to determine factors contributing to SIP participants' levels of commitment to attain education and careers in biomedical fields.

Required Sample Sizes Based on Power, Effect Size, Number of Predictors (alpha = .05)

N. PREDICTORS	POWER = .8 (RECOMMENDED)		POWER = .7	
	Moderate Effect Size (Recommended)	Large Effect Size	Moderate Effect Size	Large Effect Size
12	n = 127	n = 61	n = 107	n = 53
10	n = 118	n = 57	n = 99	n = 49
8	n = 108	n = 52	n = 90	n = 44

Attachment H: Intern Log

FEASIBILITY STUDY TO CONDUCT PROCESS AND OUTCOME EVALUATIONS OF THE NHGRI SUMMER INTERNSHIP PROGRAM

To be completed online weekly through link in e-mailed reminder on Friday afternoons. Interns will be asked to keep a personal journal during the week.

Date will be created automatically.
Time should be recorded in hours.

ACTIVITY	TIME SPENT	INTEREST LEVEL (0=LOW – 5=HIGH)
Conducting research		
Learning from mentor(s)		
Reading scientific papers		
Attending SIP event(s) (specify:_____)		
Receiving career counseling		
Other (specify:_____)		
Comments:		

Attachment I: Evaluation Survey – ITO

FEASIBILITY STUDY TO CONDUCT PROCESS AND OUTCOME EVALUATIONS OF THE NHGRI SUMMER INTERNSHIP PROGRAM

ITO Evaluation of the NHGRI SIP

As you know, Capital Consulting Corporation is evaluating the NHGRI Summer Internship Program (SIP). As a valued stakeholder in this evaluation, we ask for your help in guiding our understanding of the program.

Your candid responses on the following survey will greatly assist us in providing you with information that will help provide the best possible experience to future interns. If you have any questions about this survey, please contact _____**TBD**.

Thank you for taking the time to complete this survey.
Today's date: _____

1. How many summer interns did you have this past summer? ___
2. How does this number compare with participation during the past several years?
   ___ more interns this year
   ___ fewer interns this year
   ___ about the same number of interns this year as in previous years
3. How many of this year's interns are from URGs? ___
4. How does this number compare with participation of interns from URGs during the past several years?
   ___ more interns from URGs this year
   ___ fewer interns from URGs this year
   ___ about the same number of interns from URGs this year as in previous years
5. How many mentors participated in the program this past summer? ___
6. How does this number compare with participation during the past several years?
   ___ more mentors this year
   ___ fewer mentors this year
   ___ about the same number of mentors this year as in previous years
7. Have there been any unanticipated situations or issues with mentors or interns this year that would affect the SIP?
   ___ No
   ___ Yes (please describe): _____
8. What do you see as the major strengths of the SIP this year? _____
   _____
9. What do you see as the major weaknesses of the SIP this year? _____
   _____
10. What additional information would help us better understand the SIP?
    _____
    _____

Attachment J: Evaluation Survey – SIP Mentors

FEASIBILITY STUDY TO CONDUCT PROCESS AND OUTCOME EVALUATIONS OF THE NHGRI SUMMER INTERNSHIP PROGRAM

Mentor Evaluation of the NHGRI SIP

The NHGRI Intramural Training Office has contracted with Capital Consulting Corporation to evaluate the NHGRI Summer Internship Program (SIP). As a valued SIP mentor, we ask for your help in guiding our understanding of the program.

Your candid responses on the following survey will greatly assist us in providing NHGRI with information that will help them provide the best possible experience to future interns. If you have any questions about this survey, please contact _____**TBD**.

Thank you for taking the time to complete this survey.

Today's date: _____

Mentor's NHGRI Branch: [ ] CGB [ ]GMBB [ ] IDRB [ ] NCGC [ ] OCD
[ ] GDRB [ ] GTB [ ] MGB [ ] NISC [ ] SBRB

1. How many summer interns did you have this past summer? ___
2. How many mentors and other researchers did each intern interact with on a daily basis during her or his summer project? ___
3. Did you mentor the students directly, or did someone in your lab mentor the interns?
   ___ I was the primary mentor.
   ___ One of my staff or fellows was the primary mentor.
   ___ Both I and others mentored them equally.
4. Regarding the nature of student involvement in your program, please check all that apply:
   ___ Interns work independently.
   ___ Interns work as part of a team.
   ___ Interns are given their own unique project or project component.
   ___ Interns are given specific tasks to accomplish.
   ___ Interns participate in weekly discussion groups to talk about their projects.
   ___ Interns develop a paper or poster describing their work at the end of the internship.
   ___ Other (Please describe: _____)
5. Did your interns provide competent help in the lab? ___ No; ___Yes; ___ N/A
   Comments: _____
6. How many of this year's interns do you anticipate will go on to further education in the biomedical field? ___
7. How many of this year's interns have asked you for a letter of recommendation? ___
8. How many of this year's interns do you expect to stay in touch with after the summer program? ___
9. How satisfied were you with your SIP mentoring experience this year?
   ___ Not at all satisfied ___ Somewhat satisfied ___ Fairly well satisfied ___ Very satisfied
   Comments: _____

10. What do you see as the major strengths of the SIP? _____
    _____
11. What do you see as the major weaknesses of the SIP? _____
    _____
12. What additional information would help us better understand the SIP?
    _____

Attachment K: Evaluation Survey – SIP Interns

FEASIBILITY STUDY TO CONDUCT PROCESS AND OUTCOME EVALUATIONS OF THE NHGRI SUMMER INTERNSHIP PROGRAM

Intern Evaluation of the NHGRI SIP

NOTE: An intern's URG status will be merged from ITO records. Ensure matching items on both sides.

The NHGRI Intramural Training Office has contracted with Capital Consulting Corporation to evaluate the NHGRI Summer Internship Program (SIP). As a valued SIP participant, we ask for your help in guiding our understanding of the program.

Your candid responses on the following survey will greatly assist us in providing NHGRI with information that will help them provide the best possible experience future to interns.

Please record your first, instinctive answer, even if you do not think it is "politically correct." Do not think about what your answers "should" be. All responses will be coded by an identifying number only, kept confidential, and analyzed in group form so that no personal information is revealed. If you have any questions about this survey, please contact _____**TBD**.

Some questions may seem similar to others. However, we ask that you answer all questions to help ensure the reliability of the assessment. Thank you for taking the time (estimated at _____ minutes) to complete this survey.

First initials of first and last names: ___ ___ Birthdate: ____/ ____/ ____

Last four digits of your Social Security Number: _____ Today's date:____/ ____/ ____

Permanent Residence: City:_____; State: _____

NHGRI Assignment Branch: [ ] CGB [ ] GMBB [ ] IDRB [ ] NCGC [ ] OCD
[ ] GDRB [ ] GTB [ ] MGB [ ] NISC [ ] SBRB

Section I: Respondent Profile

1. Gender: [ ] Male [ ] Female

2. Education Level:
   - [ ] High School Junior
   - [ ] High School Senior
   - [ ] College Freshman
   - [ ] College Sophomore
   - [ ] College Junior
   - [ ] College Senior
   - [ ] Graduate Student
   - [ ] Medical Student

3. Major/primary field of study:
   - [ ] Biological Sciences
   - [ ] Biomedical Field
   - [ ] Other (please specify) _____

4. How many times have you participated in the NHGRI SIP?
   - [ ] None – this is my first year
   - [ ] One time before this
   - [ ] Two or more times before this

5. Father's level of education:

[ ] Some high school	[ ] College graduate
[ ] High school diploma	[ ] Some graduate school
[ ] Some college	[ ] Graduate school degree

6. Mother's level of education:

[ ] Some high school	[ ] College graduate
[ ] High school diploma	[ ] Some graduate school
[ ] Some college	[ ] Graduate school degree

7. Is anyone in your family a biomedical professional?
   [ ] Yes (please describe): _____
   [ ] No

8. Does a parent or relative work in the biomedical fields at NIH?
   [ ] Yes [ ] No

9. Were you acquainted with any of the NHGRI faculty prior to applying for the SIP?
   [ ] Yes (please describe): _____
   [ ] No

10. Why did you apply to the SIP this year? (Please check all that apply.)
    ___ A friend or family member works at NIH and suggested the program.
    ___ I was interested in learning more about biomedical research.
    ___ It was a paying job for the summer.
    ___ The experience would look good on my vita/resume.
    ___ Other (please describe): _____

Section II: Background

1. How much education have you had in biomedical science?
   [ ] None
   [ ] Very little
   [ ] Some
   [ ] Quite a bit
   [ ] Extensive

2. How much previous experience have you had working in a lab?
   [ ] None
   [ ] Very little
   [ ] Some
   [ ] Quite a bit
   [ ] Extensive

3. How much prior research experience have you had?
   [ ] None
   [ ] Very little
   [ ] Some
   [ ] Quite a bit
   [ ] Extensive

4. What kind of prior research experience have you had?

___ None.
___ I have studied experimental research methods.
___ I have designed a research project.
___ I have helped with some phases of a research project.*
___ I have helped with many phases of a research project.*
___ I have conducted a research project by myself.*
___ I have conducted ___ (number) of research projects by myself.*

*Please describe your role in the research projects you have participated in: _____
_____

5. To what extent have you:

	NEVER	I'VE STUDIED THIS.	I'VE HELPED A LITTLE.	I'VE HELPED A LOT.	I'VE DONE THIS MYSELF A LITTLE.	I'VE DONE THIS MYSELF A LOT.
a. Developed a testable question or hypothesis (a tentative explanation for a scientific problem) to be answered through an investigation?						
b. Reviewed existing literature to determine prior knowledge, research, and/or evidence from previous investigations that address the question or hypothesis?						
c. Identified or determined the factors (variables) in an investigation that could affect the results?						
d. Developed specific methods for collecting information about the factors (variables)?						
e. Planned data analysis strategies to address research questions or hypotheses?						
f. Identified all the materials needed for completing the investigation?						
g. Developed a logical set of directions or guidelines to complete the investigation?						
h. Tested the data collection materials to ensure their validity and reliability?						
i. Obtained required clearance or permission to conduct the investigation?						
j. Conducted the investigation according to the guidelines?						
k. Kept careful notes about procedures or unusual occurrences?						
l. Repeated a procedure several times to ensure validity and reliability?						
m. Collected data according to the specific methods developed?						
n. Analyzed the data according to planned strategies?						
o. Formed a conclusion based on results of data analysis?						
p. Developed a presentation or summary						

	NEVER	I'VE STUDIED THIS.	I'VE HELPED A LITTLE.	I'VE HELPED A LOT.	I'VE DONE THIS MYSELF A LITTLE.	I'VE DONE THIS MYSELF A LOT.
report based on study results?						
q. Presented findings at a meeting or conference?						
r. Written a paper of study findings for publication in a peer-reviewed journal?						
s. Had a research paper published in a peer-reviewed journal?						

6. Which type(s) of research experiences have you had? (Please check all that apply.)

___ I've worked in a research lab.
___ I've conducted behavioral science research.
___ Other (please describe): _____

7. Right now, how committed are you to pursuing a career in the biomedical field?

___ I definitely will.
___ I probably will.
___ I may.
___ I may not.
___ I probably will not.
___ I definitely will not.

8. Considering steps toward a career in the biomedical field, have you or will you:

	I ALREADY HAVE.	I DEFINITELY WILL.	I PROBABLY WILL.	I MAY.	I PROBABLY WILL NOT.	I DEFINITELY WILL NOT.
a. Applied to undergraduate programs with strong scientific training for the biomedical field?						
b. Majored in biomedicine?						
c. Applied to graduate school to study biomedicine?						
d. Attended graduate school for a master's degree in biomedicine?						
e. Attended graduate school for a Ph.D. in biomedicine?						
f. Applied to medical school?						
g. Attended medical school?						
h. Participated in internships or other training in the biomedical field?						
i. Sought a job/position in the biomedical field?						
j. Held a job/position in the biomedical field?						

Section III: Capability

1. Please circle the number that best describes how prepared you feel to perform the following:
(1 = Not prepared, 2 = Minimally prepared, 3 = Slightly prepared, 4 = Moderately prepared, 5 = Fairly well prepared, 6 = Well prepared, 7 = Quite well prepared)

		Not Prepared						*Quite Well Prepared*
a.	Ask appropriate questions	1	2	3	4	5	6	7
b.	Keep a good lab notebook	1	2	3	4	5	6	7
c.	Conduct an experiment independently	1	2	3	4	5	6	7
d.	Conduct an experiment reproducibly	1	2	3	4	5	6	7
e.	Work cooperatively with others	1	2	3	4	5	6	7
f.	Create and communicate possible solutions to problems	1	2	3	4	5	6	7
g.	Analyze data	1	2	3	4	5	6	7
h.	Synthesize information	1	2	3	4	5	6	7
i.	Communicate findings clearly at a meeting	1	2	3	4	5	6	7
j.	Communicate findings clearly in a poster	1	2	3	4	5	6	7

2. How much do you feel you now know about:
(1 = Nothing, 2 = Very little, 3 = A little, 4 = A moderate amount, 5 = A fair amount, 6 = Quite a bit, 7 = Very much)

		Nothing						*Very Much*
a.	Biomedical science	1	2	3	4	5	6	7
b.	How to plan an experiment	1	2	3	4	5	6	7
c.	How to conduct an experiment	1	2	3	4	5	6	7
d.	How to work with others on an experiment	1	2	3	4	5	6	7
e.	How to solve problems that may occur with an experiment	1	2	3	4	5	6	7
f.	How to keep accurate records	1	2	3	4	5	6	7
g.	How to plan data analyses	1	2	3	4	5	6	7
h.	How to analyze data	1	2	3	4	5	6	7
i.	How to summarize findings	1	2	3	4	5	6	7
j.	How to present findings clearly	1	2	3	4	5	6	7

Section IV: SIP Experience (postinternship and followup surveys only)

1. For each of the following statements, please indicate your response on the scale from "Strongly Disagree" (1) to "Strongly Agree" (7). ? = Don't Know

Statements	***Strongly Disagree***						***Strongly Agree***	***Don't Know***
a. I have a good understanding of biomedical science.	1	2	3	4	5	6	7	?
b. Before I participated in the NHGRI Student Intern Program (SIP), I already was committed to pursuing a career in biomedical science.	1	2	3	4	5	6	7	?
c. My experience at NIH helped me understand what is involved in biomedical research.	1	2	3	4	5	6	7	?
d. Lab work is not for me.	1	2	3	4	5	6	7	?
e. Workshops, seminars, and other SIP opportunities are very helpful.	1	2	3	4	5	6	7	?
f. I have learned a tremendous amount about conducting biomedical research.	1	2	3	4	5	6	7	?
g. I have received good contact information for pursuing next steps.	1	2	3	4	5	6	7	?
h. I have received a lot of career counseling in biomedical science.	1	2	3	4	5	6	7	?
i. I feel comfortable working in a lab.	1	2	3	4	5	6	7	?
j. I intend to pursue education and/or career opportunities in the biomedical sciences.	1	2	3	4	5	6	7	?
k. NHGRI faculty and staff are too busy to help me much.	1	2	3	4	5	6	7	?
l. I have good ideas about how to proceed with the next step in my education and/or career.	1	2	3	4	5	6	7	?
m. I have received a lot of mentoring.	1	2	3	4	5	6	7	?
n. I am able to make good decisions on scientific projects.	1	2	3	4	5	6	7	?
o. I have good role models for a career in biomedical science.	1	2	3	4	5	6	7	?
p. If I didn't understand something during my internship, there was no one to ask for help.	1	2	3	4	5	6	7	?
q. I can make a valuable contribution to biomedical science.	1	2	3	4	5	6	7	?
r. My experience with the SIP clarified my interest in biomedical research.	1	2	3	4	5	6	7	?
s. Sometimes all the work involved with the SIP was overwhelming.	1	2	3	4	5	6	7	?
t. Biomedical research is interesting to me.	1	2	3	4	5	6	7	?
u. Workshops, seminars, and other opportunities external to work in my lab were **not** helpful.	1	2	3	4	5	6	7	?
v. My NHGRI SIP experience clarified my level of interest in biomedical research.	1	2	3	4	5	6	7	?
w. I will follow up with contacts I have been given for furthering my education and/or career.	1	2	3	4	5	6	7	?
x. I intend to keep in touch with my NIH mentor(s).	1	2	3	4	5	6	7	?
y. I will participate in the NHGRI SIP again if I have the opportunity.	1	2	3	4	5	6	7	?
z. I am committed to pursuing a career in biomedical science.	1	2	3	4	5	6	7	?

2. Please rate the extent to which your experience with the SIP has affected your:

	GREATLY INCREASED	SOMEWHAT INCREASED	NO EFFECT	SOMEWHAT DECREASED	GREATLY DECREASED
a. Understanding of the biomedical sciences					
b. Confidence in your ability to conduct biomedical research					
c. Interest in biomedical science					
d. Understanding of potential career opportunities					
e. Contacts for taking next steps.					
f. Commitment to obtain additional education in the biomedical field					
g. Commitment to pursue a career in the biomedical field					

3. The following questions concern the work environment during your internship:

   a. How many mentors did you work with most of the time? ___

   b. Did you find your mentors to be good role models? ___ No ___ Yes
   Comments: _____

   c. Do you intend to maintain your relationship with your SIP mentor(s)? ___ No ___ Yes

   d. Do you intend to request a letter of recommendation from your SIP mentor(s)? ___ No ___ Yes

   e. On a scale of 1 to 10, where 1 = awful and 10 = fantastic, how would you rate your SIP mentoring experience? ___

   f. What percentage of your time did you work:
   ___ independently
   ___ as part of a team
   ___ other (specify): _____)
   (NOTE: These should sum to 100% of your work time with the SIP.)

   g. Were you given your own research project or project component?
   ___ No
   ___ Yes (please describe):_____

   h. Did you participate in discussion sessions regarding your project?
   ___ No
   ___ Yes (please describe):_____

   i. Did you make a presentation at journal club meetings?
   ___ No
   ___ Yes (please describe):_____

   j. Did you develop and present a paper or poster session describing your work?
   ___ No
   ___ Yes (please describe):_____

   k. Did you learn about career opportunities you intend to pursue?
   ___ No
   ___ Yes (please describe):_____

l. To what extent did you gather resources/make contacts to transition to the next level in your education and/or career?
___ I did not receive any helpful information.
___ I cannot use any of the information I received. (please describe):_____)
___ I may use some of the information.
___ I will use the information I received. (Please describe specific information and how you intend to use it.):
_____

m. Which of the additional workshops, seminars, and other opportunities did you find **most** helpful?
_____

n. Which of the additional workshops, seminars, and other opportunities did you find **least** helpful?
_____

4. How satisfied were you with your SIP experience this year?
___ Not at all satisfied, ___ Somewhat satisfied, ___ Fairly well satisfied, ___ Very satisfied
Comments: _____

5. Which of the following factors contributed to making your SIP experience a **good** one? (Please check all that apply.)
___ Relationship with mentor(s)
___ Relationships with other interns
___ Nature of the work I was involved with/project(s) I worked on
___ Amount I learned
___ Exposure to resources and contacts
___ Other (please describe):_____

6. Which of the following factors contributed to making your SIP experience a **bad** one? (Please check all that apply.)
___ Relationship with mentor(s)
___ Relationships with other interns
___ Nature of the work I was involved with/project(s) I worked on
___ Amount I learned
___ Exposure to resources and contacts
___ Other (please describe):_____

7. What were the highlights of your NHGRI SIP experience? _____
_____
_____

8. What would you suggest be done differently in the future? _____
_____
_____

Thank you for your help.

Attachment L: OMB and IRB Clearance Information

FEASIBILITY STUDY TO CONDUCT PROCESS AND OUTCOME EVALUATIONS OF THE NHGRI SUMMER INTERNSHIP PROGRAM

PRA/OMB Clearance Process

Information source: http://www.hhs.gov/ocio/policy/collection/infocolsub.html

The Paperwork Reduction Act (PRA) requires the Office of Management and Budget (OMB) to clear any planned collection of information from the public. To comply with the PRA and its implementing regulations, Federal agencies must complete an Information Collection Request (ICR), which consists of a set of documents that describe what information is needed, why it is needed, how it will be collected, and how much collecting the information will cost the respondents and the Government. The sponsor OPDIV for the collection of information from the public is responsible for completing the ICR.

- When required: An ICR must be completed, and OMB approval must be granted for any situation where 10 or more respondents are involved and the questions are standardized in nature.
- Exceptions: Information collected from Federal employees
- Process:
  - 60-day Federal Register Notice
  - ICR Package (Supporting Statement + Attachments)
  - 30-day Federal Register Notice
  - Package Review by OPDIV and U.S. Department of Health and Human Services (HHS) PRA Offices
  - HHS Review and Submission to OMB
  - OMB and OPDIV Pass–Back Period
  - OMB Action
- Timeline: The total ICR process takes approximately 6-9 months from beginning to end.
- Contact: Mikia Currie, Program Analyst, Project Clearance Branch, Office of Extramural Research/NIH/HHS, (301) 435-0941, mc401w@nih.gov (The Project Clearance Branch is the NIH control point for OMB clearance functions concerning public information collection activities.)

Steps To Complete the ICR Process

- 60-day Federal Register Notice: Inform the public of your intent to ask for clearance for the collection of information and solicitation of comments for a 60-day period. Consult with your OPDIV RCO for an example specific for your OPDIV. At this time a “draft” ICR must also be developed, which includes the Supporting Statement and all supporting documents. This is important because documents should be ready for review by the public if requested during the 60-day public comment period.
- ICR Supporting Statement and Attachments: A Supporting Statement includes narrative information explaining the purpose, scope, and benefit(s) of the collection. Items generally included in the supporting statement include:
  - Cite the authorizing legislation (public law, executive order, etc.) or the pertinent regulation if the collection is being carried out pursuant to a proposed rulemaking.
  - The Supporting Statement must include an explicit reference to the operating unit’s information quality guidelines, as required by the Data Quality Act.
  - Cite the initial 60-Day Federal Register notice informing the public of the proposed information collection and solicitation of comment.
  - Attachments should include the data collection instrument form, questionnaire, survey, interview guide, telephone interview script, or other instruments that will be used for the collection; any instructions for completing information collection; and introductory and followup

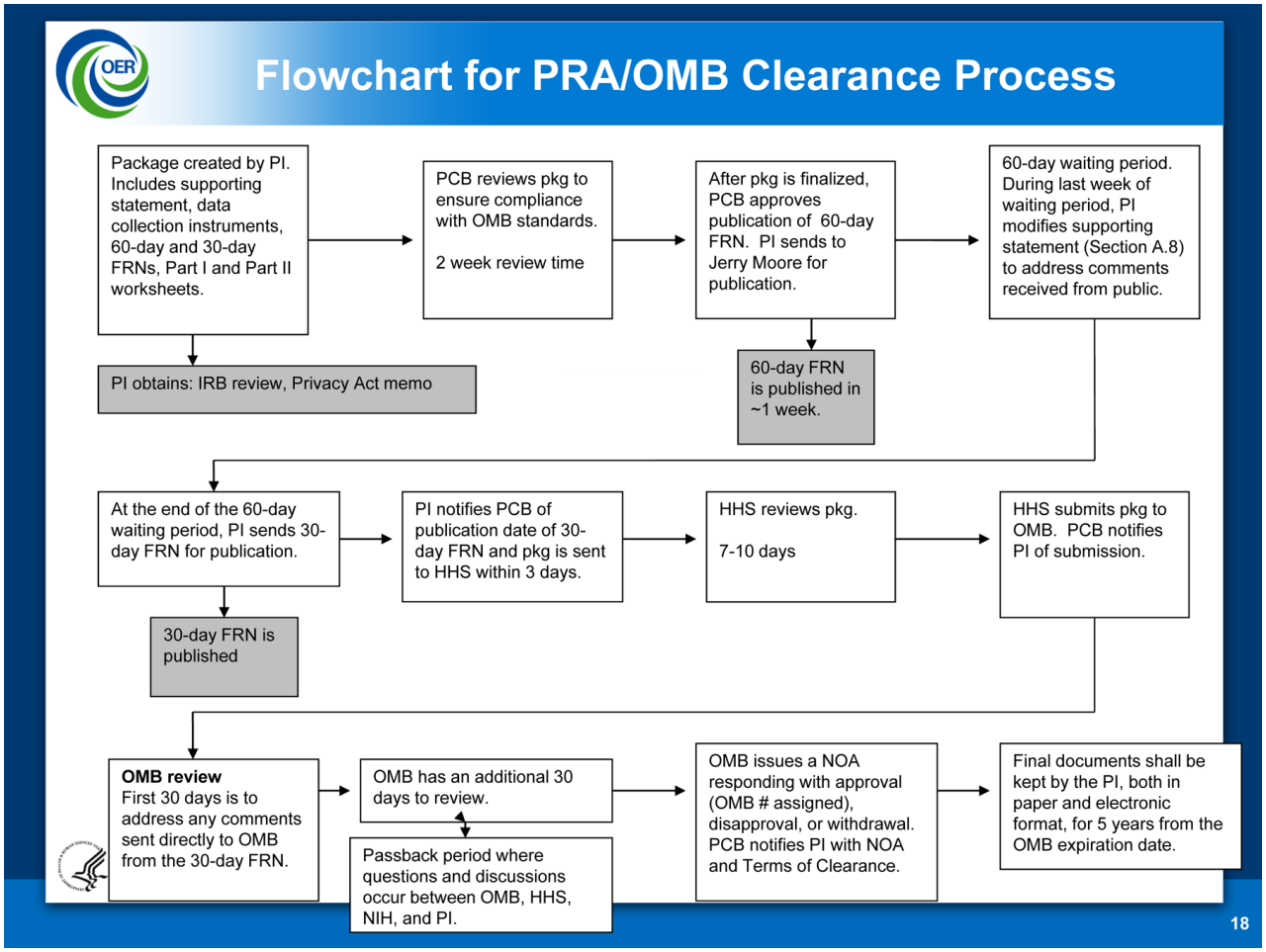
letters to respondents. If Institutional Review Board (IRB) approval is needed, include the IRB letter of approval for research involving human subjects. Also include any additional backup information necessary to explain the procedures described in Part B of the Supporting Statement.
    - The Supporting Statement is divided into two parts: Part A (Justification) and Part B (Statistical Methodology). Part A is mandatory for all supporting statements; Part B is required for all supporting statements that involve statistical methods.
- 30-day Federal Register Notice: This second opportunity for public comment notifies the public that the clearance request has been submitted to OMB and that the public has an opportunity to comment on the final version of the ICR and that public comments must go to OMB. Publication of the 30-Day Federal Register Notice should occur prior to the ICR submission to HHS.
- Package Review by OPDIV and HHS PRA Offices: The draft ICR must be reviewed and approved by the OPDIV PRA Office. Once the package has been reviewed by the OPDIV PRA Office and the 30-Day Federal Register Notice has been published, the OPDIV then submits the ICR and all related documentation to HHS via www.PaperworkReduction.gov. The HHS RCO reviews and finalizes the request for submission to OMB. At this point, an ICR can be retracted back to the OPDIV if all documents cannot be certified by the HHS RCO.
- HHS Review and Submission to OMB: Once the ICR is finalized and approved by the HHS RCO, the ICR is submitted from HHS through ICRAS to OMB's ROCIS system. The OPDIV PRA Office will receive an e-mail confirming receipt by OMB, and an e-mail will be sent to the program staff as well. Once OMB has received the ICR, the 60-Day OMB review period begins.
- OMB and OPDIV Pass–Back Period: During the 60-Day OMB review period, discussions or negotiations concerning the ICR may occur between the program OPDIV and OMB by either conference call or e-mail. Comments received from the public during this review period can also be discussed at this time. The HHS RCO may be involved if necessary during this period.
- OMB Action: At the conclusion of the 60-Day OMB review, OMB issues a Notice of Action (NOA). The OMB NOA contains one of three responses: Approval, Disapproval (with a process for appeal), or Withdrawal. Additionally, terms of clearance can be attached to the ICR.

Additional Resources

- Great Q&As: http://www.whitehouse.gov/sites/default/files/omb/inforeg/pmc_survey_guidance_2006.pdf
- Great information: http://www.hhs.gov/ocio/policy/collection/index.html

Types of Surveys

- Generic Clearance: Simple customer satisfaction surveys where the results will be used for internal NIH purposes only.
- Outcome/Impact/Needs Assessment/Other: Collect data for the purposes of quantifying achievements of program outputs and outcomes; assessing the proportion of outcomes that can be attributed to the program instead of other influences; estimating the needs of prospective markets that the program can meet with improvements to its design (exclusive of satisfying the needs of existing markets with the program in its current form).

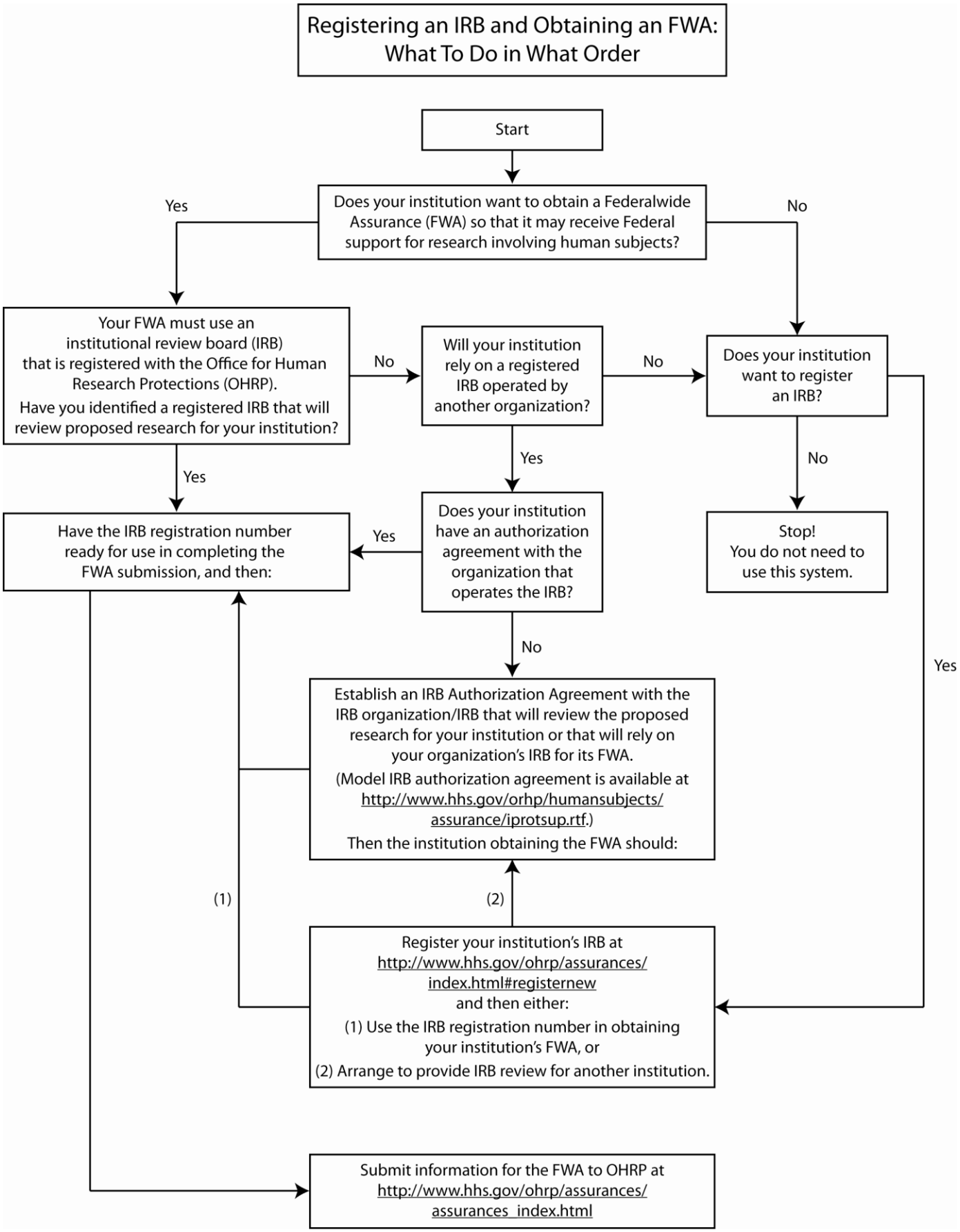

Flowchart for PRA/OMB Clearance Process
Package created by PI. Includes supporting statement, data collection instruments, 60-day and 30-day FRNs, Part I and Part II worksheets.
PCB reviews pkg to ensure compliance with OMB standards.
2 week review time
After pkg is finalized, PCB approves publication of 60-day FRN. PI sends to Jerry Moore for publication.
60-day waiting period. During last week of waiting period, PI modifies supporting statement (Section A.8) to address comments received from public.
PI obtains: IRB review, Privacy Act memo
60-day FRN is published in ~1 week.
At the end of the 60-day waiting period, PI sends 30-day FRN for publication.
PI notifies PCB of publication date of 30-day FRN and pkg is sent to HHS within 3 days.
HHS reviews pkg.
7-10 days
HHS submits pkg to OMB. PCB notifies PI of submission.
30-day FRN is published
OMB review
First 30 days is to address any comments sent directly to OMB from the 30-day FRN.
OMB has an additional 30 days to review.
Passback period where questions and discussions occur between OMB, HHS, NIH, and PI.
OMB issues a NOA responding with approval (OMB # assigned), disapproval, or withdrawal. PCB notifies PI with NOA and Terms of Clearance.
Final documents shall be kept by the PI, both in paper and electronic format, for 5 years from the OMB expiration date.
18

IRB Clearance Process

- An Institutional Review Board (IRB) registration is effective for 3 years.
- Electronic Submission System for Federalwide Assurances (FWAs) and IRB Registrations: http://ohrp.cit.nih.gov/efile/Default.aspx
- Contact: Charmaine Anderson, Assurance/IRB Coordinator, Office for Human Research Protections/HHS, (240) 453-8210, charmaine.anderson@hhs.gov

Additional Resources

- Great Q&As: http://answers.hhs.gov/ohrp/categories/1565
- NIH IRB Information: http://ohsr.od.nih.gov/irb/index.html


Registering an IRB and Obtaining an FWA: What To Do in What Order
Start
Does your institution want to obtain a Federalwide Assurance (FWA) so that it may receive Federal support for research involving human subjects?
Yes
No
Your FWA must use an institutional review board (IRB) that is registered with the Office for Human Research Protections (OHRP).
Have you identified a registered IRB that will review proposed research for your institution?
No
Will your institution rely on a registered IRB operated by another organization?
No
Does your institution want to register an IRB?
Yes
No
Yes
Yes
Does your institution have an authorization agreement with the organization that operates the IRB?
Have the IRB registration number ready for use in completing the FWA submission, and then:
Yes
Stop! You do not need to use this system.
No
Yes
Establish an IRB Authorization Agreement with the IRB organization/IRB that will review the proposed research for your institution or that will rely on your organization's IRB for its FWA.
(Model IRB authorization agreement is available at http://www.hhs.gov/orhp/humansubjects/assurance/iprotsup.rtf.)
Then the institution obtaining the FWA should:
(1)
(2)
Register your institution's IRB at http://www.hhs.gov/ohrp/assurances/index.html#registernew
and then either:
(1) Use the IRB registration number in obtaining your institution's FWA, or
(2) Arrange to provide IRB review for another institution.
Submit information for the FWA to OHRP at http://www.hhs.gov/ohrp/assurances/assurances_index.html