Washington University in St. Louis

Human Research Protection Office

Barnes Jewish Hospital
St. Louis Children's Hospital
Washington University

IRB ID #: 201203111

To: Sarah Elgin

From: The Washington University in St. Louis Institutional Review Board,
WUSTL DHHS Federalwide Assurance #FWA00002284
BJH DHHS Federalwide Assurance #FWA00002281
SLCH DHHS Federalwide Assurance #FWA00002282

Re: Assessment of the Genomics Education Partnership Survey of Prior Students

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Approval Date: 04/09/12

Next IRB Approval Due Before: N/A

Type of Application:	**Type of Application Review:**	**Approved for Populations:**
☒ New Project	☐ Full Board:	☐ Children
☐ Continuing Review	Meeting Date:	☐ Prisoners
☐ Modification	☐ Expedited	☐ Pregnant Women, Fetuses, Neonates
	☒ Exempt	☐ Wards of State
	☐ Facilitated	☐ Decisionally Impaired

Source of Support:
Howard Hughes Medical Institute
Pre college and undergraduate Science Education Program

MATERIALS APPROVED

Consent/Assent Materials:

Consent & Assent Forms

Preamble-1.rtf.doc

Recruitment/Advertisement Materials:

Recruitment Script: Email

Email for Alumni Students.rtf

Questionnaires:

Subject Data Collection Instruments

Student.Alumni.Survey.GEP.docx

This approval has been electronically signed by IRB Chair or Chair Designee:
Erin Wingbermuehle, BA
04/09/12 1532

IRB Approval: IRB approval indicates that this project meets the regulatory requirements for the protection of human subjects. IRB approval does not absolve the principal investigator from complying with other institutional, collegiate, or departmental policies or procedures.

Recruitment/Consent: Your IRB application has been approved for recruitment of subjects not to exceed the number indicated on your application form. If you are using written informed consent, the IRB-approved and stamped Informed Consent Document(s) are available in *my*IRB. The original signed Informed Consent Document should be placed in your research files. A copy of the Informed Consent Document should be given to the subject. (A copy of the *signed* Informed Consent Document should be given to the subject if your Consent contains a HIPAA authorization section.)

Continuing Review: Federal regulations require that the IRB re-approve research projects at intervals appropriate to the degree of risk, but no less than once per year. This process is called "continuing review." Continuing review for non-exempt research is required to occur as long as the research remains active for long-term follow-up of research subjects, even when the research is permanently closed to enrollment of new subjects and all subjects have completed all research-related interventions and to occur when the remaining research activities are limited to collection of private identifiable information. Your project "expires" at midnight on the date indicated on the preceding page ("Next IRB Approval Due on or Before"). You must obtain your next IRB approval of this project by that expiration date. You are responsible for submitting a Continuing Review application in sufficient time for approval before the expiration date, however you will receive reminder notice prior to the expiration date.

Modifications: Any change in this research project or materials must be submitted on a Modification application to the IRB for prior review and approval, except when a change is necessary to eliminate apparent immediate hazards to subjects. The investigator is required to promptly notify the IRB of any changes made without IRB approval to eliminate apparent immediate hazards to subjects using the Modification/Update Form. Modifications requiring the prior review and approval of the IRB include but are not limited to: changing the protocol or study procedures, changing investigators or funding sources, changing the Informed Consent Document, increasing the anticipated total number of subjects from what was originally approved, or adding any new materials (e.g., letters to subjects, ads, questionnaires).

Unanticipated Problems Involving Risks: You must promptly report to the IRB any unexpected adverse experience, as defined in the IRB/HRPO policies and procedures, and any other unanticipated problems involving risks to subjects or others. The Reportable Events Form (REF) should be used for reporting to the IRB.

Audits/Record-Keeping: Your research records may be audited at any time during or after the implementation of your project. Federal and University policies require that all research records be maintained for a period of seven (7) years following the close of the research project. For research that involves drugs or devices seeking FDA approval, the research records must be kept for a period of three years after the FDA has taken final action on the marketing application, if that is longer than seven years.

Additional Information: Complete information regarding research involving human subjects at Washington University is available in the "Washington University Institutional Review Board Policies and Procedures." Research investigators are expected to comply with these policies and procedures, and to be familiar with the University's Federalwide Assurance, the Belmont Report, 45CFR46, and other applicable regulations prior to conducting the research. This document and other important information is available on the HRPO website http://hrpohome.wustl.edu/.

IRB	Behavioral/Social Science
IRB ID #	201203111
Title	Assessment of the Genomics Education Partnership Survey of Prior Students
Short Title	GEP Survey of Prior Students
PI	Sarah Elgin
Status	Open

Create Form

Modification/Update Form
Continuing Review Form
Modification/Update + Continuing Review Form
Reportable Event Form
Project Close Form

Subjects

# Approved	1000
Minors	No
Pregnant/Fetus	N/A
Cognitively Impaired	N/A
Prisoners	N/A

FDA

IND Numbers	N/A
IDE Number	N/A
HDE Number	N/A
Non-Significant Risk Device	N/A
Emergency Use	N/A

Review

Next Approval Due By	
Closed to Accrual	No

Other

Certificate of Confidentiality	N/A
IRB Authorization Agreement	N/A
Unaffiliated Investigator Agreement	N/A

History

Form	Received	Agenda Date	Type	Status	Basket	Other Review
New	03/20/12		Exempt	Approved on 04/09/12		Completed

GEP Survey of Prior Students

PI: Sarah Elgin
IRB ID #: 201203111

Project Details

I. Demographics

I.1 ***Project Title:***
Assessment of the Genomics Education Partnership
Survey of Prior Students

I.2 ***Short Title (required):***
GEP Survey of Prior Students

I.3 ***Project is primarily:***
Behavioral/Social Science

I.4 ***Do you want the IRB to give this project***
Exempt status

I.6 ***Enter the estimated date you will be ready to begin recruiting participants or collecting data for this project.***
04/2012

I.7 ***Provide a short summary of the purpose and procedures of the study proposed in this IRB application.***

- ***DO NOT include information on studies not proposed in this application. (If your source of support proposal describes multiple aims, refer to the information button for an example on how to complete this question.)***
- ***Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.***
- ***DO NOT cut and paste technical abstracts from source of support applications that may not be understood by a general audience.***

Will send an email to former students who participated in the GEP program to assess the value of the GEP associated course and gather data about their current employment

I.8 ***Specify your research question(s), study aims or hypotheses (do not indicate "see protocol")***
Students working with the Genomics Education Partnership currently participate in a voluntary pre/post-course survey to assess their attitudes toward science and to report the gains they achieved by participating in this research experience, and a pre/post-course quiz to assess their increased understanding of the organization and function of genes and genomes. Prof. Elgin and other faculty involved in the GEP would now like to determine how these students value the course one or more years after the event, and have devised a "Survey of GEP Student Alumni." Primarily, this human subjects research is intended to gather information on the long-term educational value and career impact of the GEP research experience as implemented in standard education settings at colleges and universities. While having students do research in

genomics sounds rather specialized, we believe that this approach allows students to develop an understanding of basic concepts and tools underlying molecular genetics and genomics that they do not gain (or retain) from lecture-based courses on the same topic. Further, we hope the experience will encourage students to maintain or develop an interest in biology research, and will increase their confidence in their own abilities to engage in research. The survey has been developed to gather information on the student's current occupation, and the degree to which they feel that the GEP experience helped them to attain their goals. The research aims include: 1) evaluating the effectiveness of the GEP approach in providing students with a memorable research experience; and, 2) empirically exploring the value of a genomics education program in an upper level laboratory course from an educational and career perspective. The results of this evaluation will be reported to the science and science education communities at large in addition to being published in journals and books as appropriate.

I.9 ***Background and significance and/or Preliminary studies related to this project.***
(do not indicate "see protocol")

Bio 4342/434W, Research Explorations in Genomics, is designed to provide an opportunity for undergraduate students to participate in genomics research. This course is being used as a prototype by the Genomics Education Partnership (GEP), a collaborative venture by a growing number of primarily undergraduate institutions and the Biology Dept and Genome Institute of Washington University in St. Louis. Participating undergraduates learn to take raw sequence data to high quality finished sequence, and to annotate genes and other features, leading to analysis of a question in genomics and research publication. GEP organizes research projects and provides training/collaboration workshops for PUI faculty and teaching assistants. Workshops are fully supported, including participant travel, by a grant from the Howard Hughes Medical Institute (HHMI) to Professor Sarah C R Elgin (grant application previously submitted).

The advent of genomics technologies has changed the way biomedical scientists study genome organization, regulation of gene expression, and evolution. As such, scientists now analyze massive volumes of data to track events within an entire genome and to compare one genome to another. To keep pace with these developments, undergraduate students in fields related to or contained within the biomedical sciences must be introduced to these new and powerful tools and to this new way of thinking about doing research in these fields early on in their college education. At the same time, it is important that the students maintain an appreciation for and understanding of the biology associated with this massive amount of data. Working scientists construct experiments to answer questions, but too few students are given the opportunity to experience discovery research because of the resource-intensive nature of fundamental research. Incorporating research into an academic year semester-long lab course allows us to provide this experience to more students.

The GEP supports collaborative projects on sequence improvement and annotation, with sequencing improvement being carried out in the spring semester each year. Currently we are focusing on finishing and annotation of the dot chromosomes of different Drosophila species. The raw sequencing data (taken from public databases) is posted on the GEP server in student-sized packages,

along with instructional materials, training exercises, and computer tools to allow students to take ownership of a segment of DNA. Each student is then able to call for additional reads (sequencing reactions) as needed to finish their segment to a high level of accuracy. The WU Genome Institute carries out these sequencing reactions and posts the additional data for student use. At Washington University, we have found that each student can finish one fosmid (40-50 kb) in the first half of the semester in a lab course meeting 8 hr/wk. Participating in sequence enhancement is challenging, but very satisfying for students, as they contribute new knowledge to the public databases used by scientists and students alike.

During the second half of the semester, the WU students annotate their fosmid sequence, using BLAST and other tools to identify genes, repetitious sequences, and other features. Students may also use Clustalw to create multiple alignments, doing various evolutionary comparisons, etc. Of our partner schools, some choose to participate in annotation without participating in sequence improvement. Because annotation is entirely computer-based, and relies on tools and databases available on the web, it is easy to incorporate annotation projects into a variety of teaching schedules. See the GEP website at http://gep.wustl.edu.

The results of the GEP student research are meaningful beyond the classroom. Genomics data generated by student participants is deposited in GenBank and will be used by other researchers to answer medical, ecological, and evolutionary scientific questions. Annotation of the dot chromosomes will be posted on FlyBase, the universal resource for the Drosophila research community. So far, two papers have been published with student co-authors, and a third is in preparation (see Slawson EE, et al., 2006, Genome Biol. 7(2):R15 and Leung et al., 2010, Genetics 185: 1519 - 1534).

I.10 ***Literature cited / references (if attaching a grant or protocol enter N/A).***
N/A

II. Research Team

II.1 ***The Principal Investigator of this study is:***
Faculty

II.3 ***Do you want to add a team member who is a WUSTL faculty, student or staff member?***
No

II.4 ***Do you want to add a team member who is <u>not</u> a WUSTL faculty, student or staff member?***
No

II.5 ***Team Members***

WUSTL Team Members

Role	Name	E-mail	College	Department	Contact	WUSTL COI	Consent Process Involvement
PI	Sarah Elgin, PHD	selgin@biology2.wustl.edu	Arts & Sciences	Biology	Yes		

Name	Financial Interests
Sarah Elgin, PHD	none

Non-WUSTL Team Members

Name	Institution	Location	FWA	Role	DHHS	Contact	WUSTL COI	Consent Process Involvement
Nothing found to display								

Name	Financial Interests
Nothing found to display	

III. Source(s) of Support

III.1*Source(s) of Support*

	Type	Source	Grant Title	Name of PI on Grant	Status	Status Description
	Private Foundation/Association	Howard Hughes Medical Institute	Pre college and undergraduate Science Education Program	Sarah C R Elgin	Awarded	

* new source name

III.2 ***What is the current status of this support?***

Source	Status	Other Status Description
Howard Hughes Medical Institute	Awarded	

V. Other Institutional Reviews/Requirements

V.1 ***Do you or a family member have within the past twelve months or anticipate having within the next twelve months any financial interests in the company/organization providing support for this research or from a company/organization that owns or licenses the drug, device, or intellectual property being utilized in this research?***

Name	Financial Interests
Sarah Elgin, PHD	none

V.4 ***Do any of the objectives of this study involve the diagnosis, prevention, screening, evaluation or treatment of cancer?***
No

V.5 ***Are more than 30% of the patients involved in this study likely to have cancer as their diagnosis?***
No

VI. Participants

VI.1 ***How many adult participants do you expect to consent for this***

project?
1000

VI.4 ***How many minor participants do you expect to consent for this project?***
0

VI.7 ***Describe EACH of your participant populations***

- ***Include description of any control group(s)***
- ***Specify the Inclusion/Exclusion criteria for EACH group***

The student participants will be those enrolled in Bio 4342/434W Research Explorations in Genomics in prior years (from 2005 to the present). These students were typically juniors and seniors when they took the course, majoring in biology, biochemistry, or computer science. Similar students take GEP-connected courses at other colleges and universities. The distribution of race, gender, and ethnicity should reflect that of the students majoring in these subjects.

VI.21 ***Do you plan to recruit/enroll non-English speaking people?***
No

VII.A. Basic Project Information

VII.A.8 ***Where will project procedures take place (check all that apply)?***

- Danforth Campus

VII.A.9 ***Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?***
Yes

VII.A.10 ***What is the WUSTL site's role(s) for this project (check all that apply)?***

- Coordinating Center
- Statistical/Data Management Center

VII.A.11 ***Describe in detail the responsibilities of the WUSTL researchers relative to the overall conduct of the study.***
Design, implementation and distribution of survey

VII.A.12 ***Describe in detail the procedures that will be used to identify and report unanticipated problems from participating sites to the lead institution. Include:***

- ***the timeframe for reporting (i.e. days, weeks, etc.); and***
- ***the method of contact (i.e. email, phone, etc.)***

All problems will be addressed by the principal investigator Sarah Elgin

VII.A.13 ***Describe in detail the procedures that will be used to identify and report unanticipated problems from the lead institution to participating sites. Include:***

- ***the timeframe for reporting (i.e. days, weeks, etc.); and***
- ***the method of contact (i.e. email, phone, etc.)***

All problems will be addressed by the principal investigator Sarah

Eligin

VII.A.14 ***Describe in detail the procedures that will be used to communicate protocol modifications from the lead institution to the participating sites. Include:***

- ***the timeframe for reporting (i.e. days, weeks, etc.); and***
- ***the method of contact (i.e. email, phone, etc.)***

Any modifications will be communicated immediately to IRB and others affected immediately in writing

VII.A.15 ***Describe in detail the procedures that will be used to communicate interim results from the lead institution to the participating sites. Include:***

- ***the timeframe for reporting (i.e. days, weeks, etc.); and***
- ***the method of contact (i.e. email, phone, etc.)***

Interim results will not be communicated. Only a final report will be generated

VII.A.16 ***Describe in detail the procedures that will be used to communicate other new information which may impact a participant's willingness to participate, or continue participating from the lead institution to the participating sites. Include:***

- ***the timeframe for reporting (i.e. days, weeks, etc.); and***
- ***the method of contact (i.e. email, phone, etc.)***

All participates will be notified via email

VII.A.17 ***What are collaborating site roles for this project?***

- Statistical/Data Management Center - Dr. David Lopatto Grinell University

VII.D. Recruitment & Consent

VII.D.1 ***Check all materials/methods that will be used in recruiting participants (you will need to attach copies of all materials at the end of the application):***

- **E-mail**

VII.E. Methods

VII.E.3 ***Will any questionnaires, surveys, or written assessments be used to obtain data directly from participants in this study?***
Yes

VII.E.4 ***List all questionnaires, surveys, written assessments and ATTACH each one to the application. (NOTE: You are NOT prohibited from attaching copyrighted materials to this application)***
Survey of GEP Student Alumni

VII.E.5 ***Does this project involve creating any audiotapes, videotapes, or***

photographs?
No

VII.E.6 ***Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.***

Describe study populations separately if they will be participating in different procedures - include CONTROL population if applicable.

DESCRIBE:

- ***What participants will be asked to do/what happens in the study (in sequential order)***
- ***The time period over which procedures will occur***
- ***The time commitment for the participant for individual visits/procedures***
- ***Long-term followup and how it occurs***

For the purposes of the assessment, Dr. Elgin will invite the former Bio 4342/434W students (via email) to participate in the Genomics Education Partnership Survey on Student Alumni during April 2012. The survey will be on the GEP web site, and the students will be encouraged to participate in the survey at their convenience, completing the survey in one sitting within one hour. Submitted survey responses will be deposited into a secure database in the Dept of Biology, Washington University. These data will be analyzed by Dr. David Lopatto, a member of the project evaluation team and a faculty member of Grinnell College. Other GEP faculty will invite their students to participate in the survey as well. Only aggregate data will be reported.

A raffle will be used as an incentive for the participants to complete the GEP survey. Bio 4342/434W at WU enrolls 16 students per year. The GEP has about 70 partners, and we estimate that about 3000 students are eligible to participate; based on past participation rates we anticipate getting 1,000 responses. A $100 Amazon gift card will be sent to 5 students from the national pool of those completing the survey.

Aggregate data from a given school will be supplied to the instructor from that school. All data from the survey will be appropriately aggregated before broader dissemination to the science education community.

VII.E.9 ***Will participants be provided any compensation for participating in this study?***
Yes

VII.E.10 ***Cash***
No

VII.E.11 ***Gift Card***
Yes

VII.E.12 ***Provide name of gift card vendor:***
Amazon

VII.E.13 ***Check***

No

VII.E.14 ***Course Credit***
No

VII.E.15 ***Other***
No

VII.E.17 ***Describe the compensation plan including***

- ***Compensation amount and type per visit***
- ***Total compensation***
- ***Pro-rating for early withdrawal from study***

A raffle will be used as an incentive for the participants to complete the GEP survey. Bio 4342/434W at WU enrolls 16 students per year. The GEP has about 70 partners, and we estimate that about 3000 students are eligible to participate; based on past participation rates we anticipate getting 1000 responses. A $100 Amazon gift card will be sent to 5 students from the national pool of those completing the survey.

VII.E.18 ***Could total compensation exceed $599.00 in a calendar year for a participant?***
No

VIII. Risks

VIII.1 ***What are the risks to participants including***
- emotional or psychological
- financial
- legal or social
- physical?
No Risks

VIII.2 ***What have you done to minimize the risks?***

- ***If applicable to this study ALSO include:***
  - ***How you (members of your research team at WUSTL) will monitor the safety of individual participants.***
  - ***Include a description of the availability of medical or psychological resources that participants might require as a consequence of participating in this research and how referral will occur if necessary (e.g. availability of emergency medical care, psychological counseling, etc.)***

The students will be instructed about their right to refuse to partake in the survey in the preamble on the survey website. The survey will be web-based and entirely anonymous, with all identifiers removed, and the composite data provided to Dr. Lopatto. This information will be given in an email inviting the former students to participate, and will be posted on the opening page of the survey. Their participating in and submitting the survey will be taken as their consent.

IX. Benefits

IX.1 ***What are the direct benefits to the participant (do not include compensation)?***
To participate in future course planning

IX.2 ***What are the potential benefits to society in terms of knowledge to be gained as a result of this project?***
Better science knowledge for educational purpose

X. Privacy & Confidentiality

X.1 ***Describe your plans to protect the privacy interests of the participants during the conduct of the study including:***

- ***How will you provide a private setting during the recruitment process***
- ***How will you provide a private setting for the consent process including an opportunity for the participant to ask questions privately***
- ***Describe how interventions occur in a private setting and/or how information will be collected using methods that protect the participant's privacy.***
- ***Discuss why the information collected during the study is necessary to the conduct of the study and does not unnecessarily invade the rights of participants to privacy of their personal information.***

The participant will answer the survey at home or at their place of business at their leisure through web access.

X.2 ***Are you collecting or using the Social Security Number of any participants for any purpose?***
No

X.4 ***How will information/data be collected and stored for this study (check all that apply):***

- Electronic records (computer files, electronic databases, etc.) - Data will be collected and stored on secure servers at Washington University, Department of Biology. The anonymous data will be transmitted to Dr David Lopatto, Grinnell College, for analysis.

X.5 ***Do the confidentiality protections indicated above allow only members of the research team to access identified data/specimens?***
Yes

XI. Data Analysis

XI.1 ***Provide a summary of the analysis methods you will use, including, if applicable, the data points or outcomes you will analyze.***
The analysis of results will focus exclusively on group results. The responses will be analyzed and the mean, median, and range will be noted. In addition the results for each question (responses) may be analyzed to see if there are differences among "demographic groups" of respondents -- smaller schools verses larger schools -- in their assessment of the course.

XI.2 ***Provide the rationale or power analysis to support the number of participants proposed to complete this study.***
The participants is composed of a complete census of all participants in this program and do not represent a select sample.

XII. Future Research

XII.1 ***Do you wish to keep any information about participants involved with this research project so that other researchers outside the current study team may contact them for future research?***
No

XII.3 ***Does this project involve storing any data for future research?***
No

XII.4 ***Does this project involve storing any tissues or specimens for future research?***
No