IRB ID #: 201406129

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: Effective Implementation of a Classroom Undergraduate ResearchExperience (CURE): Testing, Optimizing, and Extending a Bioinformatics

Approval Date: 03/25/15
Next IRB Approval Due Before: 07/01/15

Type of Application:	Type of Application Review:	Approved for Populations:
New Project	Full Board:	Children
Continuing Review	Meeting Date:	Signature from one parent
Modification	Expedited	Signature from two parents
	Exempt	Prisoners
	Facilitated	Pregnant Women, Fetuses, Neonates
		Wards of State
		Decisionally Impaired

Criteria for approval are met per 45 CFR 46.111 and/or 21 CFR 56.111 as applicable.

Source of Support:
National Science Foundation
Effective Implementation of a Classroom Undergraduate Research Experience (CURE)

MATERIALS APPROVED

Consent/Assent Materials:

Consent & Assent Forms

- mod consent document-rev4.rtf
- consent document-rev2.rtf
- consent document-rev3.rtf
- consent document-rev1.rtf

Questionnaires:

Subject Data Collection Instruments

- GEP_pre_course_2015.docx
- GEP_quiz_B_revised.docx
- GEP_quiz_A_revised.docx
- GEP_post_survey_2015.docx

This approval has been electronically signed by IRB Chair or Chair Designee:
Carissa Minder, BSN, RN
03/25/15 1235

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://hrpo.wustl.edu/.

CURE

PI: Sarah Elgin
IRB ID #: 201406129

Mod Checklist

XIV.1 ***Does this modification require additional description/justification for the IRB to understand the changes being proposed?***
No

Other Mod and/or Comments

XIII.1 ***Most modifications should be made in the appropriate section (see Index) of the project itself. If you need to describe other changes, or wish to add comments about something you changed, please do so here.***
1. Added question:
What is your age?
018 yr old or older
017 yr old or younger
Reason: we need to identify minor participants to discard this data.
2. Your ethnicity answer variants were
• Caucasian
• Asian
• Afro-American
• Hispanic or Latino
• Native American
• Mixed
• Other
• NA
We have replaced these answers with
0 White
0 Asian (including Philippino)
0 Black / Afro-American (not of Hispanic origin)
0 Hispanic or Latino (including persons of Mexican, Puerto Rican, Cuban, and Central or South American origin)
0 American Indian or Alaskan Native
0Native Hawaiian or Other Pacific Islander
0 Other
0 NA
according to NSF standards.
3. We have added a list of specialties to the question Have you declared a major or concentration yet?:
0Life sciences (biology, biochemistry, neurobiology, or similar)
0Environmental studies or similar
0Physical sciences (physics, chemistry, E&PS, math, or similar)
0Computer science
0Engineering (other than computer science)
0Social sciences
0Humanities
0A double major including a science major
0A double major NOT including a science major
0Other
0NA
Reason: to improve data processing
4. We have removed the whole sections: Reasons for taking a course; Course elements; Which of the following experiences of research have you already had before taking this course?
5. We have removed section with descriptive statements.

Reasons: to reduce the volume of survey, avoid 'survey fatigue' affecting the quality of data, and focus on other issues.
6. We have added new sections: Enjoyment of science courses, Interest in science beyond the classroom, and Career interest in science

Modifications

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):***

Old Value (with Track Changes)

- **Other , Describe**

  Having professor ask students to log on to the website and complete surveys rather than actually recruiting using the website itself. Students are asked to complete the pre-course survey and pre-course quiz during the first week of classes. The purpose of the study is explained, and the various safeguards and opt-out mechanisms are described. This is done on the first day of class; at the second class meeting (a laboratory session), time is allowed at the end of class for students to access the
- **Website , Provide URL**

  http://gep.wustl.edu

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):***

New Value

- **Other , Describe**

  Having professor ask students to log on to the website and complete surveys rather than actually recruiting using the website itself. Students are asked to complete the pre-course survey and pre-course quiz during the first week of classes. The purpose of the study is explained, and the various safeguards and opt-out mechanisms are described. This is done on the first day of class; at the second class meeting (a laboratory session), time is allowed at the end of class for students to access the

Attachments

Old Value

Attachment Name	Category	Ver	Size		Attached
consent document-rev1.rtf	Consent & Assent Forms	6	43 k	E	08/25/14
consent document-rev2.rtf	Consent & Assent Forms	6	44 k	E	08/25/14
consent document-rev3.rtf	Consent & Assent Forms	6	43 k	E	08/25/14
mod consent document-rev4.rtf	Consent & Assent Forms	8	44 k	E	08/25/14
ElginNSFFastlanefinalprintout (2).pdf	Funding Source Grant	1	1 M	E	06/25/14
FW internal deliberations regarding the IUSE proposals.pdf	Funding Source Status of Other	2	138 k	E	06/26/14
GEP_quiz_A_revised.docx	Subject Data Collection Instruments	5	1 M	E	08/25/14

GEP_quiz_B_revised.docx	Subject Data Collection Instruments	4	1 M	E	08/25/14
Post-course_survey.pdf	Subject Data Collection Instruments	1	385 k	E	06/27/14
Pre-course_survey.pdf	Subject Data Collection Instruments	1	328 k	E	06/27/14
Prev IRB approval.pdf	Miscellaneous	1	2 M	E	06/25/14
This is the previous IRB approval we were looking to modify but it is pre-electronic version and there is no option to modify it on this system.					
assurance-document.pdf	Assurance Document	2	617 k	E	06/26/14

New Value

	Attachment Name	Category	Ver	Size		Attached
	consent document-rev1.rtf	Consent & Assent Forms	6	43 k	E	08/25/14
	consent document-rev2.rtf	Consent & Assent Forms	6	44 k	E	08/25/14
	consent document-rev3.rtf	Consent & Assent Forms	6	43 k	E	08/25/14
	mod consent document-rev4.rtf	Consent & Assent Forms	8	44 k	E	08/25/14
	ElginNSFFastlanefinalprintout (2).pdf	Funding Source Grant	1	1 M	E	06/25/14
	FW internal deliberations regarding the IUSE proposals.pdf	Funding Source Status of Other	2	138 k	E	06/26/14
*	GEP_post_survey_2015.docx	Subject Data Collection Instruments	2	139 k	E	03/19/15
*	GEP_pre_course_2015.docx	Subject Data Collection Instruments	2	84 k	E	03/19/15
	GEP_quiz_A_revised.docx	Subject Data Collection Instruments	5	1 M	E	08/25/14
	GEP_quiz_B_revised.docx	Subject Data Collection Instruments	4	1 M	E	08/25/14
	Prev IRB approval.pdf	Miscellaneous	1	2 M	E	06/25/14
	This is the previous IRB approval we were looking to modify but it is pre-electronic version and there is no option to modify it on this system.					
	assurance-document.pdf	Assurance Document	2	617 k	E	06/26/14

Asterisk indicates modified attachment.

Enrollment as Reported on Previous Forms

Type	Approval Date	Total Subjects Approved by IRB	Total Subjects Reported	Enrollment Stopped

Mod	03/25/15	300		
Mod	08/25/14	300		
Mod	08/15/14	300		
New	07/02/14	300		

Form Content

I. Demographics

I.1 ***Project Title:***
Effective Implementation of a Classroom Undergraduate Research Experience (CURE): Testing, Optimizing, and Extending a Bioinformatics

I.2 ***Short Title (required):***
CURE

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

I.4 ***Do you want the IRB to give this project***
Regular (expedited or full board) review

I.7 ***Enter the estimated date you will be ready to begin recruiting participants or collecting data for this project.***
09/2014

I.8 ***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.***

We are engaged in providing undergraduates with a research experience in genomics through a semester-long laboratory course, Bio 4342/434W Research Explorations in Genomics. We are partnering with over 100 colleges and universities across the country in this effort. The goals of this proposal are to determine the best instructional practices to optimize this research experience for our undergraduates, and to develop additional instructional materials to make the research experience in genomics more accessible for beginning college/university students. To assess the efficacy of our practice, we ask students to do a pre-/post-course quiz on genes and genomes, and to respond to a pre-/post survey that asks about their scientific interests and about their course-based research experience. Both the quizzes and the surveys are administered through a web-based site. Information gained will help us to improve the learning experience for our students, and may aid other faculty interested in designing a course-based research experience for undergraduates using other types of scientific investigations.

I.9 ***Specify your research question(s), study aims or hypotheses (do not indicate "see protocol")***
Aim 1: we will develop the GEP as a research organization,identifying and testing strategies to maximize the effectiveness of a bioinformatics-based CURE, in the
process generating a better understanding of how research experiences impact student learning and self-identification as a scientist.

Aim 2: we will develop a modified version of our curriculum and engagement strategy to make

bioinformatics-based genome research more accessible to beginning college/university students, with testing in years 2/3.

I.10 ***Background and significance and/or Preliminary studies related to this project. (do not indicate "see protocol")***

The Genomics Education Partnership (GEP) is a collaboration between a growing number of primarily undergraduate institutions and the Biology Dept and Genome Sequencing Center 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. The 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 NSF. 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 education career. 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.

I.11 ***Literature cited / references (if attaching a grant or protocol enter N/A).***

N/A

I.12 ***Select up to three key words below that best describe this research study:***

- Education
- Biology

II. Research Team

II.0 ***Principal Investigator***

Name	E-mail	College
Sarah Elgin	selgin@email.wustl.edu	Arts & Sciences

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@email.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
	Federal Agency	National Science Foundation	Effective Implementation of a Classroom Undergraduate Research Experience (CURE)	Sarah C Elgin	Awarded	

* new source name

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

Source	Status	Other Status Description
National Science Foundation	Awarded	

IV. Waiver of Consent

IV.1 ***Are you requesting a waiver of informed consent (participants will not be given <u>any</u> oral or written information about the study <u>prior</u> to their participation)?***
No

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, treatment or support of cancer patients?***
No

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

VI. Participants

VI.1 ***How many adult participants do you expect to consent for this project?***
300

VI.2 ***What is the age of the youngest adult participant?***
19.0

VI.3 ***What is the age of the oldest adult participant?***
23.0

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***

Participants are Washington University undergraduates who have enrolled in Bio 4342/434W Research Explorations in Genomics. These students are most often juniors and seniors, majoring in biology, biochemistry, or computer science. Occasionally we will have a sophomore enroll. A control group of students is also recruited. These are Washington University students who have completed the same pre-requisite courses (Bio 2960/2970, required of all biology majors), but are NOT taking Bio 4342/434W. Generally these will be students enrolled in a different upper-level Biology lab course, Consequently these will be primarily juniors and seniors who are majoring in biology, biochemistry, or similar subject areas.

VI.8 ***Describe why you believe there is a sufficient number of potential participants available to meet your recruitment goals.***
This class is one of several upper-level lab courses available to Biology majors, and every major is required to take one such lab. The course enrolls 14-16 students every year (capped at 16).

VI.9 ***Describe how you will have access to each of your study populations in sufficient number to meet your recruitment goals.***
The professor of the class will ask students to participate in this study.

VI.10 ***Choose the appropriate description of the disease/condition under study (for example consider race, ethnicity, gender, socioeconomic status etc.)***
The disease/condition under study is represented equally throughout the population

VI.13 ***Will participants provide any information about their relatives or another person (third party)?***
No

VI.16 ***Will any individual(s), other than the participant, provide you with information about the participant (e.g. proxy interviews)?***
No

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

VI.24 ***Do you propose to enroll any of the following in this study as participants?***

- ***Employee of the PI or employee of a research team member***
- ***Individual supervised by PI or supervised by member of research team***
- ***Individual subordinate to the PI or subordinate to any member of the research team***
- ***Student or trainee under the direction of the PI or under the direction of a member of the***

research team

Yes

VI.25 ***Provide justification for why these participants must be included in the study.***
Recruited students are enrolled in a class taught by the PI, Dr. Elgin.

VI.26 ***Is this project <u>about</u> pregnant women?***
No

VI.27 ***Will this project involve fetuses?***
No

VI.28 ***Does this project involve adult participants who may be incompetent or have limited decision-making capacity on initial enrollment into the study?***
No

VI.33 ***Does this project involve participants who may lose the capacity to consent for themselves over the course of the study?***
No

VI.38 ***Does this project involve participants who may regain the capacity to consent for themselves?***
No

VI.41 ***Does this project involve prisoners as participants?***
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)?***
No

VII.C. Genetic Research

VII.C.1 ***Does this project involve any research on genes or genetic testing/research?***
No

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):***

- **Other , Describe**
  Having professor ask students to log on to the website and complete surveys rather than actually recruiting using the website itself. Students are asked to complete the pre-course survey and pre-course quiz during the first week of classes. The purpose of the study is explained, and the various safeguards and opt-out mechanisms are described. This is done on the first day of class; at the second class meeting (a laboratory session), time is allowed at the end of class for students to access the

VII.D.8 ***Will a member of the research team discuss the study with the participant in person prior to the participant agreeing to participate?***
No

VII.D.10 ***Will a member of the research team discuss the study with the participant by phone prior to the participant agreeing to participate?***
No

VII.D.13 ***Check all materials that will be used to obtain/document informed consent:***

- Letter or Information sheet containing elements of consent

VII.D.14 ***Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?***

Examples:

- ***Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.***
- ***Participants will be provided with false information regarding the particular behaviors of interest in the research.***
- ***Procedures include a confederate pretending to be another participant in the study.***
- ***Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.***
- ***Study is designed to introduce a new procedure (or task) that participants are not initially told about.***

No

VII.D.25 ***Are you requesting a waiver of documentation of consent (either no participant signature or no written document)?***
Yes

VII.D.26 ***Choose <u>one</u> of the following to indicate why you are requesting that the IRB waive the requirement to obtain a participant signature as documentation of consent:***
A. The research presents no more than <u>minimal risk</u> (minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)

AND

The study involves no procedures for which consent is normally required outside of a research context. *(This type of waiver is often permitted for a minimal risk mail-out survey that includes a cover letter with all elements of consent, and returning the survey indicates consent. You cannot request this waiver if the study also involves the use of any <u>protected health information (PHI)</u>.)*

VII.D.27 ***Explain why this meets the chosen criteria in A. or B. above:***
Minimal risk because we are asking them to complete quizzes and surveys that are de-identified and this activity does not normally require consent outside of research.

VII.D.28 ***<u>Before</u> the participant gives consent to participate are there any screening questions that you need to directly ask the potential participant to determine eligibility for the study?***
No

VII.D.34 ***After*** ***the participant agrees to participate (signs consent), are there any screening procedures, tests, or studies that need to be done to determine if the participant is eligible to continue participating?***
No

VII.D.36 ***Discuss how much time a potential participant will have to agree to consider participation and whether or not they will be able to discuss the study with family/friends before deciding on participation.***
Subjects will have a few days between being presented information and having to make a decision to participate.

VII.D.37 ***How long after the participant agrees to participate do study procedures begin?***
Immediately

VII.D.38 ***Provide a description of the enrollment and consent process for adult participants***

- ***Describe each study population separately including control population***
- ***Include when recruitment and consent materials are used***
- ***Use THIRD person active voice. For example, "the principal investigator will identify potential participants, the study coordinator will discuss the study with participants over the telephone and schedule the first study visit, etc..."***
- ***Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process***

The subjects are presented with the study in class by their professors, and are given the link to go to the website and read the consent form. They are given the option to contact the PI to discuss any questions that they may have.

VII.E. Methods

VII.E.1 ***Will participants be randomized?***
Yes

VII.E.2 ***Describe randomization scheme/assignment including ratio such as 1:1, 2:1 etc.***
Some of the subjects will receive quiz A at the pre-course stage. Will then receive quiz B post course. And other subjects will receive quiz B initially and then Quiz A in the post- course stage.

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)***
– the pre-course survey, the post-course survey, and quizzes A and B. Note that a student taking the pre-course quiz is randomly assigned to A or B; when they return for the post-course quiz, they are assigned to the other quiz.

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***

Students are asked to complete the pre-course survey and pre-course quiz during the first week of classes. The purpose of the study is explained, and the various safeguards and opt-out mechanisms are described. This is done on the first day of class; at the second class meeting (a laboratory session), time is allowed at the end of class for students to access the website and participate in the survey and quiz, if they choose to do so. Nobody monitors the student activity, so those who choose to opt out can simply continue their lab work, surf the web, or do other work. This strategy allows sufficient time so that any concerned student has the opportunity to discuss the survey/quiz with Dr Elgin in private. A similar procedure is used at the end of the semester for the post-course survey and quiz. A student taking the pre-course quiz is randomly assigned to A or
> B; when they return for the post-course quiz, they are assigned to the other quiz.

VII.E.7 ***Will you attempt to recontact participants who are lost to follow-up?***
No - followup is not required in this study

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***

Students will enter into a Raffle for the chance to win a $50.00 Amazon gift card.

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?
Breach of Confidentiality

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.)***
  - ***Provide a description of the procedures being performed already for diagnostic or treatment purposes.***

The personal identification code provided by the student is converted into a hashed identification code using a cryptographic hash function (SHA256). This conversion is done on the client-side (i.e. on the web browser using the JavaScript jquery.sha256 library: https://github.com/alexweber/jquery.sha256) prior to data transmission to the Biology Department servers. Hence the original name or ID provided by the student is not part of the submitted data. However, each unique identification code provided by the student will produce a unique digest, which allow us to match the pre and post course data.

IX. Benefits

IX.1 ***What are the direct benefits to the participant (do not include compensation)?***
Participant Benefits for students:
1. Gain experience with bioinformatics tools, genomic analysis, working with large data sets;
2. Develop analytical skills while gaining a better understanding of genes and genomes;
3. Gain a sense of how research is accomplished, how new knowledge is created in this field;
4. See oneself as a scientist, have greater confidence in asking questions, exploring the unknown;
5. For those returning completed projects, become a co-author on a genomics research paper

IX.2 ***What are the potential benefits to society in terms of knowledge to be gained as a result of this project?***
The GEP is already making important contributions to the science education literature, providing evidence that a CURE in genomics can have the same impact in developing an understanding of how science is done as a summer research experience (Lopatto et al. 2008, Science 322: 684;Shaffer et al. 2014, CBE-Life Sci Edu,13: 111-130). Capitalizing on the diversity of partners and implementation approaches in the GEP, we will identify and test "best practices" that help students "think like scientists" and self-identify as members of a scientific community. Lessons learned should contribute to our foundational knowledge on
how to help our students to acquire the intellectual habits and self-confidence that lead to success in the sciences.

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.

Completion of the survey will resemble more of a "review of the class" and therefore no consent. The surveys are periodically reviewed by Dr Elgin and colleagues in the GEP to insure that only information that will be used in subsequent analysis and publication is collected. This includes some demographic information of interest to educators (sex, ethnicity), and attitudes toward science education as shown in the submitted documents.

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.) - In order to match the pre and post course results, students are asked to provide a personal identification code when they participate in the surveys and quizzes. Confidentiality is maintained by applying a cryptographic hash function (SHA256) to this identification code prior to data transmission. The application of the cryptographic hash function means that it is computationally infeasible for the GEP staff to determine the original identification code based on the hashed identification code (i.e. digest). Only the hashed identification code is stored with the survey data. Both the GEP surveys and quizzes are hosted on a Washington University Biology Department server (biology4.wustl.edu) that is maintained by Frances Thuet (thuet@wustl.edu), the Senior Computer Systems Manager of the Biology Department. The survey data are stored on the same server. GEP staff members do not have physical or remote access to this system.

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.***
Except for items that collect demographic or categorical data or that provide text boxes asking for comments, all items across all surveys ask participants to indicate their feelings/responses on a 1-5 scale. We treat these responses as numerical data. All averages are reported as means, and errors are reported as +/- 2 SEM; significance is determined at $p < 0.05$. To compare classroom-based GEP responses with those from control or other groups, we use an independent-groups t test. To test for correlation between institutional characteristics and student learning outcomes (both surveys and quizzes), we apply multiple linear regression using IBM SPSS Statistics Version 20. To look for any differences between groups of students with respect to both knowledge and learning gains, we use one-factor analysis of variance (between groups). Text comments are evaluated by looking for common themes and critical words. Quiz answers are scored as correct or incorrect using the rubric supplied by the faculty.

XI.2 ***Provide the rationale or power analysis to support the number of participants proposed to complete this study.***
Data collected from Washington University students is pooled with data from other students participating at other schools (for which IRB approval has been obtained for these surveys/quizzes from the home school). The pooled data is from several hundred students and has been shown to be meaningful by several criteria. See Shaffer et al. (2014) CBE-Life Science Education 13: 111-130 for further details (http://www.lifescied.org/content/13/1/111.full).

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

XIII. Other Mod and/or Comments

XIII.1 ***Most modifications should be made in the appropriate section (see Index) of the project itself. If you need to describe other changes, or wish to add comments about something you changed, please do so here.***
1. Added question:
What is your age?
018 yr old or older
017 yr old or younger
Reason: we need to identify minor participants to discard this data.
2. Your ethnicity answer variants were
• Caucasian
• Asian
• Afro-American
• Hispanic or Latino
• Native American
• Mixed
• Other
• NA
We have replaced these answers with
0 White
0 Asian (including Philippino)
0 Black / Afro-American (not of Hispanic origin)
0 Hispanic or Latino (including persons of Mexican, Puerto Rican, Cuban, and Central or South American origin)
0 American Indian or Alaskan Native
0Native Hawaiian or Other Pacific Islander
0 Other
0 NA
according to NSF standards.
3. We have added a list of specialties to the question Have you declared a major or concentration yet?:
0Life sciences (biology, biochemistry, neurobiology, or similar)
0Environmental studies or similar
0Physical sciences (physics, chemistry, E&PS, math, or similar)
0Computer science
0Engineering (other than computer science)
0Social sciences
0Humanities
0A double major including a science major
0A double major NOT including a science major
0Other
0NA
Reason: to improve data processing
4. We have removed the whole sections: Reasons for taking a course; Course elements; Which of the following experiences of research have you already had before taking this course?
5. We have removed section with descriptive statements.
Reasons: to reduce the volume of survey, avoid 'survey fatigue' affecting the quality of data, and focus on other issues.
6. We have added new sections: Enjoyment of science courses, Interest in science beyond the

classroom, and Career interest in science

XIV. Mod Checklist

XIV.1 ***Does this modification require additional description/justification for the IRB to understand the changes being proposed?***
No

Project Modification Attachments

Attachment Name	Category	Ver	Size		Attached
consent document-rev1.rtf	Consent & Assent Forms	6	43 k	E	08/25/14
consent document-rev2.rtf	Consent & Assent Forms	6	44 k	E	08/25/14
consent document-rev3.rtf	Consent & Assent Forms	6	43 k	E	08/25/14
mod consent document-rev4.rtf	Consent & Assent Forms	8	44 k	E	08/25/14
ElginNSFFastlanefinalprintout (2).pdf	Funding Source Grant	1	1 M	E	06/25/14
FW internal deliberations regarding the IUSE proposals.pdf	Funding Source Status of Other	2	138 k	E	06/26/14
GEP_post_survey_2015.docx	Subject Data Collection Instruments	2	139 k	E	03/19/15
GEP_pre_course_2015.docx	Subject Data Collection Instruments	2	84 k	E	03/19/15
GEP_quiz_A_revised.docx	Subject Data Collection Instruments	5	1 M	E	08/25/14
GEP_quiz_B_revised.docx	Subject Data Collection Instruments	4	1 M	E	08/25/14
Prev IRB approval.pdf	Miscellaneous	1	2 M	E	06/25/14
This is the previous IRB approval we were looking to modify but it is pre-electronic version and there is no option to modify it on this system.					
assurance-document.pdf	Assurance Document	2	617 k	E	06/26/14