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: 08/20/15
Next IRB Approval Due Before: 05/02/16

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

Consent 1 IRB stamped.rtf
Consent 2 IRB stamped.rtf
Consent 3 IRB stamped.rtf
Consent 4 IRB stamped.rtf

Recruitment/Advertisement Materials:

Recruitment: Other

Recrutiment..rtf

Questionnaires:

Subject Data Collection Instruments

GEP_pre_course_2015.docx
GEP_post_survey_2015.docx
Post_Course_Survey 2015 v5 WSP clean-1_raffle.docx
GEP_quiz_A_revised_08_05_2015_raffle.docx
GEP_quiz_B_revised_08_05_2015_raffle.docx
Pre_Course_Survey 2015.v5.WSP clean_raffle.docx

This approval has been electronically signed by IRB Chair or Chair Designee:
Jennifer Weinman, CIP, BA, MA
08/20/15 0956

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/.

Modifications to the Pre-course Survey

1. We have corrected some typographical errors in the preamble (consent document) and in the survey itself. Note that all student entries are encrypted, so that no one, not even the assessment analyst, Dr. Lopatto, can identify the entry from a particular student. This has been clarified in the text (paragraph 3) of the introduction.
Reason: these changes have been made to improve the writing and insure that the subjects understand the purpose of the survey/quiz, and know that their privacy is assured.

2. We have added "Community College" as an option in describing the list of schools, and altered the description of the leaving process accordingly.
Reason: we are now recruiting community colleges to join the GEP.

3. We have added questions on Pell grant eligibility and on whether the student is the first in their family to attend college/university.
Reason: Representation of such students is of particular interest as we seek to broaden participation in scientific research.

4. We have added a question on whether this is the first time a student has worked on a GEP project.
Reason: Some students continue over two semesters; given prior exposure, we would expect a shift in their responses, so we would like to identify these cases.

5. We have added a question concerning future goals of our community college students.
Reason: Most community colleges do not have "majors" in the same sense used in the four-year schools; hence to find out whether they are committed to a course of study in the sciences, we need a different question specifically for them.

6. We have scrambled the items from the TOSRA (Test of Science-Related Attitudes) (second group of questions under Part II, opinions).
Reason: We hope to increase the chance that the student will reflect carefully on each question, rather than responding to the block of questions.

7. We have removed the SMQ (Science Motivation Questionnaire) items (third block of questions under Part II, opinions, in the spring 2015 survey).
Reason: The results proved redundant with the TOSRA results; the TOSRA questions have been retained. This should reduce "survey fatigue," which can affect the quality of the data.

8. We have added 12 items under "Opinion," taken from AL Duckworth, C Peterson, MD Matthews, & DR Kelly (2007) "Grit: Perseverance and passion for long-term goals," *Journal of Personality and Social Psychology* 9: 1087-1101.
Reason: There is considerable interest in whether "grit" is associated with success in challenging endeavors, such as the undergraduate research project we are studying here.

Modifications to the Post-course Survey

1. All of the above modifications occur on the post-course survey as well.

2. Under "Learning Experiences" we have deleted questions asking students to comment on which GEP teaching tools or activities contributed to their learning.

Reason: Little differentiation was seen. Hence this set of questions was removed to reduce the risk of "survey fatigue."

3. Four specific questions were added under "opinions" that are designed to assess the student's sense of "ownership" of their GEP project. These questions are listed below:

- I faced challenges that I managed to overcome in completing my GEP research project.
- The findings of my GEP research project gave me a sense of personal achievement.
- In conducting my GEP research project, I actively sought advice and assistance.
- My GEP research project was interesting.

Reason: Project ownership has been cited as a critical factor in engaging students in a research program.

Modifications to the Quizzes

The second portion (Part II) of the quizzes (A and B) focuses on DNA sequence improvement, or "finishing." This portion (Part II) has been revised to reflect changes to the GEP finishing protocol. The original quiz questions were developed based on use of the Sanger sequencing protocol. However, GEP is currently working on hybrid assemblies that were produced using two different sequencing technologies (i.e. 454 and Illumina). This has allowed us to make substantial changes to the GEP finishing protocol, simplifying it. In response to this new, simplified sequence improvement protocol, we have reduced the number of questions in the finishing quiz (from 20 to 8) and modified others to reflect the
issues that the students will most often encounter during the sequence improvement of these hybrid assemblies. Part I of the quizzes (dealing with genome annotation) remains unchanged.

Other changes:

1.7 We wish to begin recruiting subjects to this new survey staring 8/2015.

VI.2: Change "age of youngest adult participant" to 18.0.
Reason: We are starting to use GEP materials with freshmen, who will typically be 18 years old. Some may still be 17 years old. The latter entries will be identified by student response to a question on their age, and will be discarded.

VI.7: Add the following language at the end of the current paragraph: Beginning in fall 2015 we are also using GEP materials in a freshman seminar, Biology 193, Investigating Eukaryotic Genomes, and will invite these students to take the quizzes and surveys as well.
Reason: We wish to study the applicability of the approach with beginning college / university students.

VI.8: Change text to "Bio 4342/434W 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 12-16 students every year (capped at 16). Bio 193 is one of several seminars available to freshmen, and is capped at 12 students. We are one of several schools participating in this study, and the aggregate student population is sufficient to address the pedagogical questions."
Reason: As noted above, the study has been expanded to include beginning students.

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

Reason: A multi-site project allows us to obtain responses from a larger number of students, working in a variety of settings, resulting in findings with greater validity.

VII.A.10. What is the WUSTL site's role(s) for this project (check all that apply)?
Change response to the following:
Statistical/Data Management Center
'Other': The student quizzes and surveys are housed on a server in the Biology Department. These sites remain open throughout the academic year; the collected responses are sent from Washington University to a consultant, Dr. David Lopatto (Grinnell College, Iowa) for analysis. Our responsibilities also include reminding the GEP faculty members to ask their students to participate in the assessment, as specified in the protocol.
Reason: Central data collection is essential for the proposed analysis.

VII.A.17 What are collaborating site roles for this project?
Clinical/participating site - IRB approval pending

XIII.1 List of modifications: see above.

Sarah C R Elgin, 8/20/15

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.
The second portion of the quizzes (A and B) focus on DNA sequence improvement, or "finishing." This portion (Part II) has been revised to reflect changes to the GEP finishing protocol. The original quiz questions were developed based on use of the Sanger sequencing protocol. However, GEP is currently working on hybrid assemblies that were produced using two different sequencing technologies (i.e. 454 and Illumina). This has allowed us to make substantial changes to the GEP finishing protocol, simplifying it. In response to this new, simplified sequence improvement protocol, we have reduced the number of questions in the finishing quiz (from 20 to 8) and modified others to reflect the issues that the students will most often encounter during the sequence improvement of these hybrid assemblies. Part I of the quizzes (dealing with genome annotation) remains unchanged.

Modifications

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

Old Value (with Track Changes)

- Coordinating Center

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

New Value

- Statistical/Data Management Center
- Other - The student quizzes and surveys are housed on a server in the Biology Department. These sites remain open throughout the academic year; the collected responses are sent from Washington University to a consultant, Dr. David Lopatto (Grinnell College, Iowa) for analysis. Our responsibilities also include reminding the GEP faculty members to ask their students to participate in the assessment, as specified in the protocol.

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

Old Value (with Track Changes)

- Clinical/participating site - IRB approval pending

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

New Value

- Clinical/participating site - IRB approval pending
- Statistical/Data Management Center - Biology Department

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_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
Post_Course_Survey 2015 v5 WSP clean-1.docx	Subject Data Collection Instruments	5	45 k	E	08/04/15
Pre_Course_Survey 2015 v5 WSP clean.docx	Subject Data Collection Instruments	5	42 k	E	08/04/15
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 1 IRB stamped.rtf	Consent & Assent Forms	7	47 k	E	08/13/15
*	Consent 2 IRB stamped.rtf	Consent & Assent Forms	7	47 k	E	08/13/15
*	Consent 3 IRB stamped.rtf	Consent & Assent Forms	7	46 k	E	08/13/15
*	Consent 4 IRB stamped.rtf	Consent & Assent Forms	9	48 k	E	08/13/15
	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
*	Recrutiment..rtf	Recruitment: Other	1	42 k	E	08/13/15
Once again the system is requiring a recruitment doc, so it has been attached and can be deleted upon your review.						
	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_08_05_2015_raffle.docx	Subject Data Collection Instruments	3	1 M	E	08/20/15
*	GEP_quiz_B_revised_08_05_2015_raffle.docx	Subject Data Collection Instruments	3	1 M	E	08/20/15
*	Post_Course_Survey 2015 v5 WSP clean-1_raffle.docx	Subject Data Collection Instruments	7	46 k	E	08/20/15
*	Pre_Course_Survey 2015.v5.WSP clean_raffle.docx	Subject Data Collection Instruments	7	43 k	E	08/20/15
	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	08/20/15	300		
Mod	08/04/15	300		
CR	05/04/15		12	No
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.
08/2015

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:
- Biology
- Education

II. Research Team

II.0 Principal Investigator

Name	E-mail	Title	School
Sarah Elgin	selgin@email.wustl.edu	Viktor Hamburger Professor in Arts & Sciences	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 **not** a WUSTL faculty, student or staff member?
No

II.5 Team Members

WUSTL Team Members

Role	Name	E-mail	Title	School	Department	Contact	WUSTL COI	Consent Process Involvement
PI	Sarah Elgin, PHD	selgin@email.wustl.edu	Viktor Hamburger Professor in Arts & Sciences	Arts & Sciences	Biology - A&s	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 any oral or written information about the study prior 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?
18.0

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 per-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. Beginning in Fall 2015 we are also using GEP materials in a freshman seminar, Biology 193, Investigating Eukaryotic Genomes, and will invite these students to take quizzes and survey's as well and some maybe 17. REASON: We wish to study the applicability of the approach with beginning college/ university students.

VI.8 Describe why you believe there is a sufficient number of potential participants available to meet your recruitment goals.
Bio 4342/434W 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 12-16 students every year (capped at 16.) Bio 193 is one of several seminars available to freshman, and is capped at 12 students. We are one of several schools participating in the study, and the aggregate student population is sufficient to address the pedagogical questions.

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

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 about 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)?
Yes

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

- Statistical/Data Management Center
- Other - The student quizzes and surveys are housed on a server in the Biology Department. These sites remain open throughout the academic year; the collected responses are sent from Washington University to a consultant, Dr. David Lopatto (Grinnell College, Iowa) for analysis. Our responsibilities also include reminding the GEP faculty members to ask their students to participate in the assessment, as specified in the protocol.

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

- Clinical/participating site - IRB approval pending
- Statistical/Data Management Center - Biology Department

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 **one** 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 minimal risk (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 protected health information (PHI).)*

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 **Before** 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.
The second portion of the quizzes (A and B) focus on DNA sequence improvement, or "finishing." This portion (Part II) has been revised to reflect changes to the GEP finishing protocol. The original quiz questions were developed based on use of the Sanger sequencing protocol. However, GEP is currently working on hybrid assemblies that were produced using two different sequencing technologies (i.e. 454 and Illumina). This has allowed us to make substantial changes to the GEP finishing protocol, simplifying it. In response to this new, simplified sequence improvement protocol, we have reduced the number of questions in the finishing quiz (from 20 to 8) and modified others to reflect the issues that the students will most often encounter during the sequence improvement of these hybrid assemblies. Part I of the quizzes (dealing with genome annotation) remains unchanged.

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 1 IRB stamped.rtf	Consent & Assent Forms	7	47 k	E	08/13/15
Consent 2 IRB stamped.rtf	Consent & Assent Forms	7	47 k	E	08/13/15
Consent 3 IRB stamped.rtf	Consent & Assent Forms	7	46 k	E	08/13/15
Consent 4 IRB stamped.rtf	Consent & Assent Forms	9	48 k	E	08/13/15
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
Recrutiment..rtf	Recruitment: Other	1	42 k	E	08/13/15

Once again the system is requiring a recruitment doc, so it has been attached and can be deleted upon your review.

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_08_05_2015_raffle.docx	Subject Data Collection Instruments	3	1 M	E	08/20/15
GEP_quiz_B_revised_08_05_2015_raffle.docx	Subject Data Collection Instruments	3	1 M	E	08/20/15
Post_Course_Survey 2015 v5 WSP clean-1_raffle.docx	Subject Data Collection Instruments	7	46 k	E	08/20/15
Pre_Course_Survey 2015.v5.WSP clean_raffle.docx	Subject Data Collection Instruments	7	43 k	E	08/20/15
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