

During the academic year 2017-2018, some GEP schools will work on genomes of particular interest to their own instructor, where the genome browser was created using G-OnRamp. We wish to contrast the attitudes and performance of these students with the GEP students as a whole. The preambles for the student quizzes and surveys have been modified accordingly to include this analysis and acknowledge funding from NIH. The Washington University IRB approval of the change is copied below, followed by the new preambles.

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: NSF IUSE #1431407: Effective Implementation of a Classroom Undergraduate Research Experience (CURE): Testing, Optimizing, and Extending a Bioinformatics

Approval Date: 05/30/17

Next IRB Approval

Due Before: 01/18/18

Type of Application:

Type of Application Review:

Approved for Populations:

New Project
Continuing Review
Modification

Full Board:
Meeting Date:
Expedited
Exempt
Facilitated

Children
Signature from one parent
Signature from two parents
Prisoners
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:

NIH

A GENOME BROWSER ON-RAMP TO ENGAGE BIOLOGISTS WITH BIG DATA

National Science Foundation

Effective Implementation of a Classroom Undergraduate Research Experience (CURE)

MATERIALS APPROVED

Consent/Assent Materials:

Consent & Assent Forms

- Consent 1 IRB stamped-nih.rtf
- Consent 4 IRB stamped-nih.rtf
- Consent 2 IRB stamped-nih.rtf
- Consent 3 IRB stamped-nih.rtf
- Consent info-Focus groups-nih.rtf

Recruitment/Advertisement Materials:

Recruitment: Other

- Recrutiment..rtf

Questionnaires:

Subject Data Collection Instruments

- 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
- GEP_pre_course_2015.docx
- GEP_post_survey_2015.docx
- Post_Course_Survey 2015 v5 WSP clean-1_raffle.docx

This approval has been electronically signed by IRB Chair or Chair Designee:
Mitchell Saulisbury-Robertson, BA, BA
05/30/17 1053

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 *myIRB*. 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/>.

Genomics Education Partnership Classroom Undergraduate Research Experiences:

Pre-course Quiz

Welcome to the GEP pre-course quiz site. You are being invited to participate in a research study. This project is a collaborative effort involving the faculty and students from many undergraduate institutions participating in the GEP. The purpose of this research is to learn more about the success of our science courses in empowering student learning. To accomplish this task we have developed a pre-course/post-course research design to measure the learning gains and other outcomes of courses that include our shared genomics project. This research is funded by the National Science Foundation. [In some cases, the class may be working with a new genome browser set up using G-OnRamp, a workflow developed to make it easier to create a genome browser for a newly sequenced genome. Development of G-OnRamp is funded by the National Institutes of Health.](#)

You are being asked to participate because you are either a GEP student or a "control" student. If you agree to participate, please complete the pre-course quiz questions by clicking the link below. You may elect not to answer individual questions. A "not applicable" or "N.A." option is available for the questions as an alternative; use this if the question is irrelevant or if you choose not to answer. You will be asked at the end of our course to complete a post course quiz as well. You will be asked to read and agree to participate in that activity prior to completing that quiz.

Because of the complexity of tracking the data from many courses in many institutions, we ask you to identify your college and course. The computer will also generate for you a personal identification code. To create this code we will ask you to enter your name as it appears on your driver's license. Your name will then be converted into an encrypted number and sent with your responses. The encryption is being done in such a way that it is not possible to convert from the number back to your name to ensure anonymity. The reason for the code is to enable us to match your pre-course quiz evaluation with a post-course evaluation that we will ask you to complete at the end of the term. This alignment of your pre-course responses with your post-course responses permits a sensitive measure of change. Your individual data will not be revealed to your course instructor. The lead analyst for the project, Prof. David Lopatto of Grinnell College, will keep all individual data confidential. Only aggregate pre-course/post-course data will be reported back to your institution and to the GEP as a whole. Your data cannot be used by instructors to determine your grade in the course.

We will keep the information you provide confidential. However, federal regulatory agencies and Washington University, including the Washington University Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research.

There are no known risks from being in this study, and you will not benefit personally. However we hope that others may benefit in the future from what we learn as a result of this study.

Taking part in this research study is completely voluntary. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify. If you change your mind about completing the quiz, just leave the site. If you have any questions about the research study, please contact Dr. Elgin at selgin@wustl.edu. If you feel that you have been harmed in any way by your participation in this study, please contact: selgin@wustl.edu. If you have questions about the rights of research participants,

please contact the Human Research Protection Office, 660 S. Euclid Ave., Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445 or email hrpo@wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

After you complete this pre-course quiz, we offer you an opportunity to be entered into a raffle for a \$50 gift certificate from Amazon.com, as a "thank you" for your participation (offer void where prohibited by law - Alabama, Hawaii, Kansas, South Carolina, Utah). Five email addresses will be selected at random in June after the academic year is over. If you wish to be entered in the raffle, we will need your email address to contact you if you win. Please be assured that the file containing this information will be completely separate from the file of quiz responses; this list of names will not be used for any other purpose.

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If you agree to participate, please fill out the pre-course survey questions by clicking the link below. You may elect not to answer individual questions. A "not applicable" or "N/A" option is available for the questions as an alternative; use this if the question is irrelevant or if you choose not to answer. You will be asked at the end of our course to complete a post- course survey as well. You will be asked to read a similar introduction and agree to participate in that activity prior to taking that survey.

Because of the complexity of tracking the data from many courses in many institutions, we ask you to identify your college and course. The computer will also generate for you a personal identification code. To create this code we will ask you to enter your name as it appears on your drivers' license. If you do not have a driver's license, use your name on your student ID card issued by your school. Your name will then be converted into a code (using a cryptographic hash function), which is used to tag your responses. The encryption is being done in such a way that it is not possible to convert this code back to your name, to ensure anonymity. The reason for the code is to enable us to match your pre-course information with a post- course evaluation that we will ask you to complete at the end of the course. This alignment of your pre-course responses with your post-course responses permits a sensitive measure of change. Your individual data cannot be revealed to your course instructor. The lead analyst for the project, Prof. David Lopatto of Grinnell College, will keep all individual data sets confidential. Only aggregate pre-course / post-course data will be reported back to your institution and to the GEP as a whole. Your data cannot be used by instructors to determine your grade in the course, and in fact cannot be identified by anyone, as only the encrypted tag is entered into the data system.

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After you complete the post-survey, we offer you an opportunity to be entered into a raffle for a \$50 gift certificate from Amazon.com, as a "thank you" for your participation (offer void where prohibited by law - Alabama, Hawaii, Kansas, South Carolina, Utah). Five email addresses will be selected at random in June, after the academic year is over. If you wish to be entered in the raffle, we will need your email to contact you if you win. Please be assured that the file containing these emails will be completely separate from the file of survey responses; this list of names will not be used for any other purpose.

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Genomics Education Partnership Classroom Undergraduate Research Experiences:

Post-course Quiz

Welcome (or welcome back) to the Genomics Education Partnership (GEP) quiz site. You are being invited to participate in a research study. This project is a collaborative effort involving faculty and students from several colleges and universities participating in the GEP. The purpose of this research is to learn more about how our science courses can empower student learning. To accomplish this task we have developed a pre-course / post-course research design to measure learning gains and other outcomes of taking a research- oriented science laboratory course including genomics. [This study is funded by the National Science Foundation. In some cases, the class may be working with a new genome browser set up using G-OnRamp, a workflow developed to make it easier to create a genome browser for a newly sequenced genome. Development of G-OnRamp is funded by the National Institutes of Health.](#)

You are being asked to participate because you are either a GEP student or a "control" student; you probably took a pre-course quiz at the beginning of the term. If you agree to participate, please complete the post-course quiz questions by clicking the link below. You may elect not to answer individual questions. A "not applicable" or "N.A." option is available for the questions as an alternative; use this if the question is irrelevant or if you choose not to answer.

Because of the complexity of tracking the data from many courses in many institutions, we asked you to identify yourself by giving your name (as it appears on your drivers license), to identify your college, and to identify your course. The computer used your name to generate an encrypted number sent with your responses. The encryption is done in such a way that it is not possible to convert from the number back to your name, to ensure anonymity. Now the reason for this identification becomes clear: we will match your pre-course quiz with your post-course quiz using your personal identification code. This alignment of your pre-course responses with your post-course responses permits a sensitive measure of change. Your individual responses will not be revealed to your course instructor. The lead analyst for the project, Prof. David Lopatto of Grinnell College, will keep all data confidential. Only aggregate pre-course / post-course data will be reported back to your institution and to the GEP as a whole. Your answers cannot affect your grade in the course.

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In a final box, after you have completed this post-course quiz, we offer you an opportunity to be entered into a raffle for a \$50 gift certificate from Amazon.com, as a "thank you" for your participation (offer void where prohibited by law - Alabama, Hawaii, Kansas, South Carolina, Utah). Five email addresses will be selected at random in June, after the academic year is over. If you wish to be entered in the raffle, we will need your email address to contact you if you win. Please be assured that the file containing this information will be completely separate from the file of quiz responses; this list of emails will not be used for any other purpose.

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Thank you very much for your consideration.

[Proceed to Survey](#)