Washington University in St. Louis

Human Research Protection Office

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

IRB ID #: 201104105

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: GEP Faculty Survey on Implementation and Sustainability ofUndergraduate Research Programs in Genomics

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Approval Date: 04/12/12

Next IRB Approval Due Before: N/A

Type of Application:

☐ New Project
☐ Continuing Review
☒ Modification

Type of Application Review:

☐ Full Board:
Meeting Date:
☐ Expedited
☒ Exempt
☐ Facilitated

Approved for Populations:

☐ Children
☐ Prisoners
☐ Pregnant Women, Fetuses, Neonates
☐ Wards of State
☐ Decisionally Impaired

Source of Support:
Howard Hughes Medical Institute
Professor's Award

MATERIALS APPROVED

Consent/Assent Materials:

Consent & Assent Forms

exempt-information-sheet.rtf

irb webintro-1.rtf.doc.rtf

Recruitment/Advertisement Materials:

Recruitment Script: Email

Email Correspondence-1.rtf

Questionnaires:

Subject Data Collection Instruments

GEP_FacultySurveyChanges.2012[2].doc

This approval has been electronically signed by IRB Chair or Chair Designee:
Diane Bohner, BSN
04/12/12 1510

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

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

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

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

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

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

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

I. Demographics

I.1 ***Project Title:***
GEP Faculty Survey on Implementation and Sustainability of Undergraduate Research Programs in Genomics

I.2 ***Short Title (required):***
GEP Faculty Survey 2

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

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

I.6 ***Enter the estimated date you will be ready to begin recruiting participants or collecting data for this project.***
04/30/2011

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

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

Faculty working with the Genomics Education Partnership are pioneers in a growing movement to introduce research into the academic year undergraduate curriculum, and are pioneers in introducing genomics into the biology curriculum.

Both of these advances pose unique challenges. As a group, we wish to assess what features of the academic climate promote and support such changes, and what features hinder them. Our goal is to generate a publication in the science education literature that will help administrators and faculty who wish to institute such changes on their own campuses. Primarily, this human subjects research is intended to assess the effort required to implement and sustain a GEP research experience for students, building on faculty experiences at a variety of colleges and universities. The assessment has been developed to collect information on the current climate on American college/university campuses, and the efforts, challenges, and satisfactions of the faculty involved in this curriculum innovation. The results of this evaluation will be reported to the science and science education communities at large in addition to being published in journals and books as appropriate.

I.8 ***Specify your research question(s), study aims or hypotheses (do not indicate "see protocol")***

Our goal is to determine features of campus organization, pedagogical structure, and collegiality that foster innovation in the biology curriculum.

I.9 ***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 Howard Hughes Medical Institute (HHMI) to Professor Sarah C R Elgin.

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.

The GEP supports collaborative projects on sequence improvement and

annotation, with sequencing improvement being carried out in the spring semester each year. Currently we are focusing on finishing and annotation of the dot chromosomes of different Drosophila species. Participating in sequence enhancement is challenging, but very satisfying for students, as they contribute new knowledge to the public databases used by scientists and students alike. Students then annotate the finished sequence, using BLAST and other tools to identify genes, repetitious sequences, and other features. Students may also use Clustalw to create multiple alignments, doing various evolutionary comparisons, etc. Of the GEP partner schools, some choose to participate in annotation without participating in sequence improvement. Because annotation is entirely computer-based, and relies on tools and databases available on the web, it is easy to incorporate annotation projects into a variety of teaching schedules. See the GEP website at http://gep.wustl.edu.

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

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

 04/16/12 07:12:53
5.2.1

We invite you to participate in a research study being conducted by investigators from Washington University in St. Louis. The purpose of the study is to assess what features of the academic climate promote and support the innovations in biology curriculum developed by the Genomics Education Partnership, and what features hinder them.

If you agree to participate, we would like you to complete the GEP Faculty Survey 2 on the GEP webpage. You are free to skip any questions that you prefer not to answer. It will take approximately 20 minutes, but no more than an hour, to complete the survey.

You will not receive course credit or payment for participation.

We will not collect your name or any identifying information about you. It will not be possible to link you to your responses on the survey. The responses will be used for aggregate analysis.

Taking part in this research study is completely voluntary. If you do not wish to participate in this study, just exit from the website at any time.

If you have any questions about the research study, please contact Sarah Elgin (selgin@biology.wustl.edu; 314-935-5348; Dept Biology CB-1137, Washington University, One Brookings Drive, St Louis, MO 63130. If you have questions about the rights of research participants, please contact the Human Research Protection Office, 660 S. Euclid Ave., Campus Box 8089, Washington University St. Louis, Saint Louis, MO 63110, (314) 633-7400, or 1-(800)-438-0445 or e-mail hrpo@wusm.wustl.edu.

Thank you very much for your consideration of this research study.

Sarah C R Elgin
Professor of Biology
Washington University in St Louis