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Indiana University of Pennsylvania Institutional Review Board
for the Protection of Human Subjects

Human Subjects Review Protocol

Investigators

Principal Investigator

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Co-Investigator(s) (e.g. thesis/dissertation committee chair; faculty sponsor, use a second sheet for any additional names)

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Position/Rank	**IUP** Email address
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address

Project Information

Date of Submission **10/15/2014**

Project Title **Assessing Student Outcomes in a CURE**

Project Type (check one) Thesis ___ Dissertation ___ Faculty Research _X_ Student Research ___ Staff Research ___

The project will be conducted from 10/30/2014 (Start date) **until** 9/20/2016 (Ending date)

Project Funding Sources (s). Indicate all that apply:

X **External Grant** **Agency Name:** **Howard Hughes Medical Institute**

____ **IUP Grant** **Type:** _____

____ **Other (describe)** _____

____ **Non-funded research**

If grant funded, application deadline or date of transmittal
(Note: Submit one copy of grant proposal as soon as it is available)

Grant funded on 12th of August, 2014

Project Description

PURPOSE, RESEARCH VARIABLES, AND POPULATION

Purpose of the study

The aim of this project is to examine the outcomes of studying in a course based research experience program (CURE). Specifically, this study will look at a particular set of student outcomes that have been specified as important for retention and persistence in science. The main and sub questions of this study are:

1. What are the outcomes of a CURE research experience?
    a. To what degree does a CURE experience develop a sense of student project ownership?
    b. To what degree does a CURE experience develop a sense of efficacy as a functioning scientist?
    c. To what degree does a CURE experience develop an identity as a scientist
    d. To what degree does a CURE experience develop an affinity with the values of a scientific community
    e. To what degree is a CURE experience different from a traditional laboratory experience in terms of project ownership, efficacy, identity and affinity to scientific values?

Background of the study

Among science educators, funding agencies and college level institutions there is broad agreement that enhancing undergraduate students scientific research experiences is of central importance. Research has shown that experiences of this kind enhance the ability to think like a scientist, understand scientific practices, design novel research and communicate like a scientist (Brewer and Smith, 2011; Duschl et al., 2007; Kardash, 2000; Laursen et al., 2010; Lopatto, 2010; Quinn et al., 2011). Furthermore, these types of experience have been shown to enhance feelings of ownership, agency and self-efficacy as a learner (Graham et al, 2013; Hanauer et al,

2012; Hanauer and Dolan 2013). Importantly these characteristics of the undergraduate research experience translate into increased retention in the sciences (Eagan et al, 2011; Hanauer et al, 2012;) and as such may offer a solution to the US President's call for increasing the number of graduates from science education programs to meet the economic needs of the US. Finally and no less importantly, these types of experience are believed to be particularly valuable for underrepresented minority students and women (Barlow and Villarejo, 2004; Eagan et al, 2011; Nagda et al. 1998).

However, research experiences – while to be greatly valued for their educational outcomes – are also relatively cost-ineffective. The traditional undergraduate research experience tends to involve apprentice-like arrangements in which students work individually with a faculty mentor, or with a graduate student or postdoctoral researcher. Although it is effective as a research-training experience, it is cost-intensive and limited to small numbers of students at relatively rich, research-intensive four-year institutions. Moreover, limited access to these opportunities does little to broaden the diversity of the larger research community. Accordingly over the last five years there have been calls and attempts to translate the undergraduate research experience (UREs) into a format that is more inclusive and applicable across classes and institutions. These attempts have come to be called Course-Based Research Experiences (CUREs) and these courses aim to offer the same benefits of a URE at a much reduced cost and in a format that should allow a wide range of students at a range of higher education institutions to participate. There are many examples of research courses developed at individual institutions, but very few that seek broader dissemination including at institutions without robust research infrastructures. The flagship program of this type is the Howard Hughes Medical Institute Science Education Alliance Phage Hunters Advancing Genomics and Evolutionary Science (HHMI SEA-PHAGES) program.

It is important to note that at this point in time we do not really know whether the CUREs offer the same educational experience as the UREs and to a very large extent the promise of the CURE has been built on research that was done in relation to UREs. A brief summary of characteristics suggests that a URE is different from a CURE. Both URE and CURE share an emphasis on discovery, usage of scientific practices, relevance of project for the scientific community and communication of science to others; but the two differ in the number of students involved, the knowledge of the instructor, the degree of mentor-student interaction, student and faculty time investment, the transmission of scientific knowledge, the quality and depth of the scientific questions explored and the ability to diverge from a predefined research trajectory. These differences suggest that outcomes of a CURE may be different from those of a URE. The current project is designed to provide an informed answer to address the student outcomes of a CURE experience.

Characteristics of the Subject Population

Age Range

The participants in this project are undergraduate students enrolled in biology or microbiology laboratory courses. The age range is 18-25

Gender

Both male and female students will be involved in the study (there are not gender restrictions in this study)

Inclusion Criteria

To participate in this study a student must be enrolled in a laboratory research course

Exclusion Criteria

There are no exclusion criteria except that to be a participant you need to be enrolled in a laboratory research course

Vulnerable Subjects

There are no vulnerable subjects in this study.

METHODS AND PROCEDURES

Method of Subject Selection

The data for this study of student outcomes in CURE courses is directed through the resources of Dr. Graham Hatfull of the Department of Biological Sciences at the University of Pittsburgh. These consist of two different initiatives. Dr. Hatfull is the director of the SEA-PHAGES program an educational research initiative funded by the Howard Hughes Medical Institute and in charge of a series of undergraduate scientific inquiry courses run at the University of Pittsburgh. Students will be contacted by email to participate in an online survey of research experiences. Dr. Hatfull, through his coordinators Dr. Nancy Kaufmann (University of Pittsburgh) & Dr. Welkin Pope (SEA-PHAGES) will contact lab instructors and request that they forward an email with the request to participate in the survey to each student. No individuating emails are recorded during this process. Dr. Hanauer does not teach and is not in any contact with the instructors or students of these courses. See Appendix A for a copy of the email to students and lab instructors. See Appendix B for a letter from Dr. Hatfull outlining his agreement and support of this submission.

Study Site

Data for this study is collected on-line using a web-based survey. The participants come from either the Biology Department of the University of Pittsburgh or members of the SEA-PHAGES program. Participants will be contacted by program coordinators Dr. Nancy Kaufmann (University of

Pittsburgh) or Dr. Welkin Pope (SEA-PHAGES program). Potential participants in the SEA-PHAGES program are situated in following list of schools: Baylor University, Brigham Young University, Brown University, Bucknell University, Cabrini College, Calvin College, Carnegie Mellon University, Carthage College, Chadron State College, College of Charleston, College of Idaho, College of St. Scholastica, College of William & Mary, Culver-Stockton College, CUNY, Queens College, Del Mar College, Doane College, Florida Gulf Coast University, Florida International University, Georgia Gwinnett College, Gettysburg College, Gonzaga University, Hampden-Sydney College, Hope College, Howard University, Illinois Wesleyan University, Indian River State College, Jacksonville State University, James Madison University, Johns Hopkins University, La Salle University, Lehigh University, Lincoln University, Loyola Marymount University, Merrimack College, Miami University, Montana Tech of the University of Montana, Montclair State University, Morehouse College, Nebraska Wesleyan University, North Carolina A&T State University, North Carolina Central University, North Carolina State University, Nyack College, Old Dominion University, Ouachita Baptist University, Providence College, Purdue University, Queensborough Community College, Saint Joseph's University, Seton Hill University, Smith College, Southern Connecticut State University, Southern Maine Community College, St. Edward's University, The Evergreen State College, The Ohio State University, Trinity College, Truckee Meadows Community College, University of Alabama at Birmingham, University of California, San Diego, University of California, Santa Cruz, University of Colorado at Boulder, University of Florida, University of Houston-Downtown, University of Kansas, University of Louisiana at Monroe, University of Maine, Fort Kent, University of Maine, Honors College, University of Maine, Machias, University of Mary Washington, University of Maryland, Baltimore County, University of North Texas, University of Pittsburgh, University of Puerto Rico at Cayey, University of Texas at El Paso, University of Wisconsin-River Falls, Virginia Commonwealth University, Washington State University, Washington University in St. Louis, Western Kentucky University, Wilkes University, and Xavier University of Louisiana

Methods and Procedures Applied to Human Subjects

Data collection for this study consists of an on-line survey. The survey will be distributed to students studying in the SEA-PHAGES program or in laboratory courses at the University of Pittsburgh. The first page of the survey has a consent form requiring explicit statement of agreement to participate. Once agreement has been attained participants are directed to the survey itself. The survey consists of 40 rating scale questions covering the following sections:

1. ***Project Ownership*** - 10 rating scales dealing with connections between the research experiences and the student (derived from Hanauer & Dolan, 2013)
2. ***Project Ownership Emotion*** – 5 rating scales dealing with specified positive emotive responses to the research experience (derived from Hanauer and Dolan, 2013)
3. ***Science Self Efficacy***- 6 rating scales dealing with the participants'

confidence in functioning as a scientist (derived from Chemers et. Al., 2010)

4. ***Science Identity*** – 5 rating scales dealing with ways in which the participant thinks about her/himself as a scientist (derived from Chemers et. Al., 2010)
5. ***Scientific Community Values*** – 4 rating scales dealing with the participant's affinity to values in the scientific community
6. ***Networking*** – 5 rating scales dealing with the discussion of their research with other parties
7. ***Future Careers*** – 5 rating scales dealing with decisions concerning a future in the sciences

The survey will be conducted in the last two weeks of the semester (November 2014 & April 2015). A full version of the tool can be found in Appendix C.

RISKS/BENEFITS

Potential Risks

Data is collected using a web-based survey tool in a voluntary manner. There do not seem to be any risks to participants involved in this study.

Protection Against Risks

The survey is voluntary and does not collect information that could be used to identify individual students. Participants can decide not to do the survey or opt out of doing the survey at any time without any instructor or institutional administrator being informed. Every effort will be made to protect data collected. It will be stored in a password protected environment

Potential Benefits

This study is designed to establish some of the potential positive outcomes of a quality introductory research experience. The study may provide insight into what these types of courses can provide and as such offer an answer to the need for large scale quality research courses for undergraduates.

Compensation for Participation

There is no compensation offered to participants

Alternatives to Participation

The study if voluntary, completed during the participants own time and web-based. If the participant chooses not to participate then they will simply not do the survey. No alternatives are necessary.

Information Withheld

No information is withheld from participants

Debriefing

At the yearly gathering of SEA-PHAGE faculty whole group results of the program will be presented. Similarly results will be presented at the Hatfull laboratory

PRIVACY/CONFIDENTIALITY

Participants are not contacted directly by the researcher (an email from the researcher is forwarded to them by the coordinator) and participant names are not recorded. All published data is reported in relation to the whole group and not in relation to individual students or specific institutions. Data is collected on the gender, ethnicity, type of school and year of study. But this data cannot be used to identify an individual student. Every effort will be made to protect the identity and privacy of the participants. Data is collected in a secure web survey format that is password protected. Downloaded data will be stored securely password protected environment.

THE CONSENT PROCESS

Consent for participation in this project involves agreement to conduct the survey on the first page of the web-based survey (see attached consent form – Appendix D). The web-based survey is designed so as not to let the participant move forward unless they explicitly agree to participate in the study following a description of the research project and the presentation of all relevant contact information.

Protected Populations and Sensitive Subjects: Indicate if any Human Subjects from the following list would be involved in the proposed activity:

☐ minors	☐ fetuses	☐ pregnant women
☐ test subjects for new drugs or clinical devices	☐ abortuses	☐ persons committing illegal behavior
☐ educationally or economically disadvantaged persons	☐ incarcerated	☐ mentally disabled

Nature of Risk.

In your judgment, does your research involve more than minimal risk? Indicate your response with an 'X' in the appropriate box

[ ] yes [X] no

Exemption Qualification

In your judgment, does your research fall under one of the six exempt categories? If you believe it does, indicate the number of the category under which you are claiming an exemption by typing an 'X' next to the relevant category.

	1. Research conducted in established or commonly accepted educational settings involving normal educational practices
X	2. Research involving the use of educational tests or surveys in a non-identifiable manner
	3. Research involving the use of educational tests or surveys with elected officials or defined by statute.
	4. Research involving the collection or study of existing data,
	5. Research and demonstration projects
	6. Taste and food quality evaluation and consumer acceptance studies

Expedited Review Qualification

In your judgment, does your project fall under one of the categories eligible for expedited review (listed below)? If you believe it does, type an 'X' next to the category under which

you are claiming expedited review.

	1. Minor modifications or additions to existing approved studies
X	2. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects
	3. The study of existing data, documents, records, pathological specimens, or diagnostic specimens
	4. Voice recordings made for research purposes such as investigations of speech defects
	5. Moderate exercise by healthy volunteers
	6. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older who are in good health and not pregnant
	7. Collection (in a non-disfiguring manner) of hair, nail clippings, and deciduous teeth; and permanent teeth if patient care indicates a need for extraction
	8. Collection for analysis of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor
	9. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. (These procedures include weighing, testing sensory acuity, electrocardiogram, electroencephalogram, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range, i.e., x-rays, microwaves.)
	10. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques
	11. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

ENCLOSURES

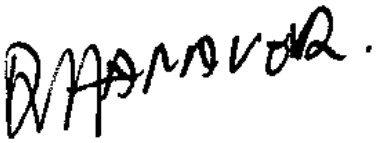
Document name/description	Number of pages
Appendix A: Student Email	1
Appendix B: Letter of Support – Prof. Graham Hatfull	1
Appendix C: Copy of Survey Instrument	6
Appendix D: Consent Form	1
Appendix E: HHMI Grant Work Scope	4

Certification

Primary Investigator

I am aware that additions to or changes in procedures involving human subjects as well as any problems connected with the use of human subjects once the project has begun must be brought to the attention of the IRB.

I agree to provide whatever surveillance is necessary to ensure that the rights and welfare of the human subjects are properly protected. I understand that I cannot initiate any contact with human subjects before I have received approval/or complied with all contingencies made in connection with the approval. I understand that as the principal investigator I am ultimately responsible for the welfare and protection of human subjects and will carry out the project as approved.



Dr. David I. Hanauer	**21/10/2014**
Signature, Principal Investigator/Program Director	date

Approval by Faculty Sponsor (required for all students):

I affirm the accuracy of this application, and I accept the responsibility for the conduct of this research and supervision of human subjects as required by law. THE PROPOSED PROJECT HAS BEEN APPROVED BY THE THESIS/DISSERTATION COMMITTEE.

Signature, Faculty Sponsor	date

FOR COMMITTEE USE ONLY

DEPARTMENT COMMITTEE RECOMMENDATION:

This project:

poses minimal risk	☐
Poses greater than minimal risk	☐
Is exempt from Continuing Review	☐
Requires Expedited review	☐
Requires full IRBPHS Review	☐

Department Committee Chairperson Signature _____ Date _____

IRBPHS decision:

☐ **Approved** ☐ **Not Approved** **to proceed**

Signature _____ Date _____