

UNIVERSITY OF MARYLAND, COLLEGE PARK
Institutional Review Board
Initial Application for Research Involving Human Subjects

Name of Principal Investigator (PI) or Project Faculty Advisor _____ Tel. No. _____
(NOT a student or fellow)

Name of Co-Investigator (Co-PI) _____ Tel. No. _____

E-Mail Address of PI _____ E-Mail Address of Co-PI _____

Name and address of contact to receive approval documents _____

Name of Student Investigator _____ Tel. No. _____

E-Mail Address of Student Investigator _____ @ _____

Check here if this is a student master's thesis or a dissertation research project

Department or Unit Administering the Project _____

Project Title _____

<p>Funding Agency: _____</p> <p>ORAA Proposal ID Number: _____</p> <p>Names of any additional Federal agencies providing funds or other support for this research project: _____</p>

Target Population: The study population will include (Check all that apply):

- | | | |
|--|------------------------------------|---|
| <input type="checkbox"/> pregnant women | <input type="checkbox"/> neonates | <input type="checkbox"/> individuals with mental disabilities |
| <input type="checkbox"/> minors/children | <input type="checkbox"/> prisoners | <input type="checkbox"/> individuals with physical disabilities |
| <input type="checkbox"/> human fetuses | <input type="checkbox"/> students | |

Exempt or Nonexempt (Optional): You may recommend your research for exemption or nonexemption by checking the appropriate box below. For exempt recommendation, list the numbers for the exempt category(s) that apply. Refer to pages 6-7 of this document.

Exempt----List Exemption Category(s) _____ *Or* Non-Exempt

If exempt, briefly describe the reason(s) for exemption.

Date _____ Signature of Principal Investigator or Faculty Advisor _____

Date _____ Signature of Co-Principal Investigator _____

Date _____ Signature of Student Investigator _____

Date _____ **REQUIRED** Departmental Signature
Name _____, Title _____
(Please also print name of person signing above)

(PLEASE NOTE: The Departmental signature block should not be signed by the investigator or the student investigator's advisor.)

Instructions for Completing the Application

The Departmental Signature block should be signed by the IRB Liaison or Alternate IRB Liaison unless there is a conflict of interest. If the Department or Unit does not have an IRB Liaison, the Department Head, Unit Head or Designee should sign the application.

Please provide the following information in a way that will be intelligible to non-specialists in your specific subject area.

1. **Abstract:** Provide an abstract (no more than 200 words) that describes the purpose of this research and summarizes the strategies used to protect human subjects. For HHS sponsored or funded research, you must submit a copy of your grant application for review.
2. **Subject Selection:**
 - a. Who will be the subjects? How will you recruit them? If you plan to advertise for subjects, please include a copy of the advertisement.
 - b. Will the subjects be selected for any specific characteristics (e.g., age, sex, race, ethnic origin, religion, or any social or economic qualifications)?
 - c. State why the selection will be made on the basis or bases given in 2(b).
 - d. How many subjects will you recruit?
3. **Procedures:** What precisely will be done to the subjects? Describe in detail your methods and procedures in terms of what will be done to subjects. How many subjects are being recruited? What is the total investment of time of the subjects? If subjects will complete surveys and/or other instruments on more than one occasion, state this in the procedures section. If you are using a questionnaire or handout, please include a copy within each set of application documents. If you are conducting a focus group, include a list of the questions for the focus group. If you plan to collect or study existing data, documents, records, pathological specimens or diagnostic specimens, state whether the sources are publicly available and if the information will be recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects. If you are collecting or studying existing data, describe the dataset and list the data elements that you will extract from the dataset.
4. **Risks and Benefits:** Are there any risks to the subjects? If so, what are these risks including physical, psychological, social, legal and financial risks? Please do not describe the risk(s) as minimal. If there are known risks, please list them. If not, please state that there are no known risks. What are the benefits? If there are known risks associated with the subject's participation in the research, what potential benefits will accrue to justify taking these risks?

5. **Confidentiality:** Adequate provisions must be made to protect the privacy of subjects and to maintain the confidentiality of identifiable information. Explain how your procedures accomplish this objective, including such information as the means of data storage, data location and duration, description of persons with access to the data, and the method of destroying the data when completed. If the research involves audio taping, videotaping or digital recordings, state who will have access to the tapes or recordings, where the tapes or recordings will be kept, and state the final disposition of the tapes or recordings (i.e. Will the tapes or recordings be destroyed? If so, when will the tapes or recordings be destroyed?). Please note that as per the University of Maryland policy on records retention and disposal, all human subject files, including work done by faculty, staff, and students, must be retained for a period of no less than 10 years after the completion of the research and can then be destroyed. Human subject files include IRB applications, approval notices, consent forms, and other related documents. For more information on records retention, go to: http://www.dbs.umd.edu/records_forms/schedule.php (Faculty and Academic Records) or contact Michelle Solter Evers, Assistant to the Director of Business Services at 301.405.9277 or mevers@mercury.umd.edu.
6. **Information and Consent Forms:** State specifically what information will be provided to the subjects about the investigation. Is any of this information deceptive? State how the subjects' informed consent will be obtained. Will you obtain informed consent in a language other than English? If so, list the language(s) in which you will obtain informed consent. Provide consent forms in all languages that will be used. Refer to the attached consent form template, sample consent form and additional consent form guidance on pages 9 to 18. If a consent form has more than one page, please add a signature and date line and the number of pages (e.g., "1 of 2," "2 of 2") to each page. Please allow a 2-inch bottom margin to accommodate the IRB approval stamp. If you plan to obtain consent over the telephone (e.g. consent for a telephone survey), include a copy of the consent script.
7. **Conflict of Interest:** Describe the potential conflict of interest, including how such a conflict would affect the level of risk to the study participants. Please consult the University of Maryland policy on conflict of interest as defined by the University of Maryland Policies and Procedures III-1.11 and II-3.10. These may be viewed at: <http://www.usmh.usmd.edu/Leadership/BoardOfRegents/Bylaws/SectionIII/III111.html>. If there is no anticipated conflict of interest, please state "No conflict of interest." This section must be included in your application.
8. **HIPAA Compliance:** State whether you are using HIPAA protected health information (PHI). Currently, researchers employed by the University of Maryland Center or who are working within or under the auspices of the University Health Center are subject to specific HIPAA requirements regarding the creation, use, disclosure, or access of PHI. Please consult the University of Maryland's Summary of HIPAA's Impact on University Research. For more information on HIPAA, go to: <http://www.hhs.gov/ocr/hipaa/> If you are not using HIPAA protected health information, please state "Not Applicable." This section must be

included in your application.

9. Research Outside of the United States: Provide responses to the following questions. Separate responses are required for each country where the research will be conducted. If you are not conducting research outside the U.S., please state “Not Applicable.” This section must be included in your application.

- a) Did the investigator(s) previously conduct research in the country where the research will take place? Briefly describe the investigator’s knowledge and experience working with the study population.
- b) Are there any regulations, rules or policies for human subjects research in the country where the research will take place? If so, please describe and explain how you will comply with the local human subject protection requirements. The United States Department of Health and Human Services, Office for Human Research Protections (OHRP) has an International Compilation of Human Subject Research Protections with a listing of the laws, regulations and guidelines of over 50 countries. This compilation can be accessed on the OHRP website: <http://www.hhs.gov/ohrp/international/HSPCompilation.pdf>
- c) Do you anticipate any risks to the research participants in the country where the research will take place, taking into account the population involved, the geographic location, and the culture? If so, please describe, including any physical, psychological, social, legal and financial risks. Do you anticipate that subjects who participate in this research will be placed at risk of criminal or civil liability? If so, please describe.

10. Research Involving Prisoners: Provide responses to the following additional IRB criteria for research involving prisoners. If you are not conducting research involving prisoners, please state “Not Applicable.” This section must be included in your application.

- a) the research under review represents one of the categories of research permissible described below;
 - i. study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
 - ii. study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
 - iii. research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults); or
 - iv. research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.
- b) any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the

- prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
- c) the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
 - d) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
 - e) the information is presented in language which is understandable to the subject population;
 - f) adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
 - g) if there is a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

SUPPORTING DOCUMENTS

Each copy of the application must include the IRB application cover sheet, the information required in items 1-10 above, and all relevant supporting documents including: consent forms, letters sent to recruit participants, questionnaires completed by participants, and any other material germane to human subjects review.

For research funded by the Department of Health and Human Services (DHHS), submit a copy of your HHS grant application. If there are discrepancies between the research proposed in your IRB application and your grant application, include a memo listing these discrepancies and the rationale for them.

NUMBER OF COPIES

Please send 1 original application including the signed cover sheet and 1 copy of the signed, original application unless your research requires full Board Review. For applications which will require review of the full Board, please submit 1 signed original application and seventeen (17) copies. Full Board reviews are required for initial applications involving greater than minimal risk to the subjects (i.e. more risk than subjects would generally encounter in their routine daily activities).

IRB Campus Mailing Address: 2100 Lee Building, Zip -5125.

IRB MEETING DATES AND APPLICATION SUBMISSION DEADLINES

To view the dates for upcoming meetings and the final date for submission of applications to be considered for each meeting, please check the following URL:
<http://www.umresearch.umd.edu/IRB/IRBdates.html>.

STATUS OF THE IRB APPLICATION

You may send an e-mail to irb@deans.umd.edu or call the IRB Office at 301-405-4212 to inquire about the status of an IRB application.

EXEMPTION CATEGORIES

(PLEASE NOTE: Exempt research must be approved by the IRB Manager, Assistant Manager or an IRB Co-Chair before data collection may begin.)

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods. **Research involving surveys or interviews with children does not qualify for exempt review. Also, this exempt category does not apply to research involving the collection of person identifiable data in which any disclosure of the data outside of the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.**
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subject's responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. **Exemption category #2 does not apply to research with children, except for research involving observations of public behavior when the investigator(s) does not participate in the activities being observed. Also, this exempt category does not apply to research involving the collection of person identifiable data in which any disclosure of the data outside of the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.**

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. **E.g. the research is conducted for the Department of Justice under Federal statute 42 U.S.C. 3789g and the research conducted for the National Center for Education Statistics under Federal statute 20 U.S.C. 12213-1, which provide certain legal protections and requirements for confidentiality.**
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects **which are conducted by or subject to the approval of Department or Agency heads**, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

If the research is funded by the United States Department of Health and Human Services, the following criteria must be met:

- a) **The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).**
- b) **The research or demonstration project must be conducted pursuant to specific federal statutory authority.**
- c) **There must be no statutory requirement that the project be reviewed by an Institutional Review Board (IRB).**

The project must not involve significant physical invasions or intrusions upon the privacy of participants.

6. Taste and food quality evaluation and consumer acceptance studies, if (a) wholesome foods without additives are consumed or (b) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

NOTE: The 6 exemption categories do not apply to research involving prisoners.

1. Project Abstract:

The purpose of this educational research project is to investigate how various pedagogical approaches help students to achieve better understanding of fundamental concepts and skills in CORE general education undergraduate science courses. This project will examine student responses to various components of the class, e.g. content, discussions, use of ELMS, office hours, quizzes, group work, etc. Students will self-report on satisfaction, attitudes, how the various components enhanced or inhibited their learning and be assessed on level of science understanding and skills. The goal is to understand what works best in various environments to increase student engagement and learning. This project will monitor the relationships of various pedagogies and student learning and attitudes.

2. Subject Selection:

Subjects are randomly self-selected by registering for CORE science courses. All students in the courses will be given the opportunity to participate in the research as subjects. Participation is voluntary. All students in the course will have the option of choosing to not participate in this study. Choosing to participate or not participate will have no effect students' grades or the amount of course work required of the student.

3. Procedures:

Participants will be asked to fill out various formative and summative surveys and respond to writing prompts. Participants may be asked to provide written journals of project activities. The surveys will ask for individual perceptions about the learning experiences, the relative value of various educational activities and the used and values of different pedagogical approaches and their understanding of science concepts and processes. Surveys such as the SALG Student Assessment of Learning Gains <http://ipconference.education.wisc.edu/> will be utilized. See attached sample documents. +

4. Risk and Benefits:

There is no presumed risk for the participants. Participants' data will be handled such that individual identity will be protected. Data provided to outside parties, will be aggregate data and not individualized, thus there is little or no risk of response identification to specific individuals. The long-term benefits will be improved teaching and learning of science by students, a better-equipped science educator workforce and a better-informed citizenry for Maryland and the US.

5. Confidentiality:

All information collected in this study is confidential and participants will not be identified by name, or other indicators of identity, unless they specifically indicate that they wish their responses to be individually cited or quoted to them. Information may be shared with representatives of the University of Maryland, College Park or governmental authorities if it is perceived that the participant or someone else is in danger or if we are required to do so by law. The collected materials will be stored in secure locations at the Center for Teaching Excellence 0405 Marie Mount Hall and/or the Office of Undergraduate Studies 2130 Mitchell Building. The materials will be held for a period of not longer than five years after which they will be destroyed.

6. Information and Consent Forms

The nature, scope, and purpose of the study will be provided to the subject on the consent form. Subjects will be encouraged to ask any questions they may have regarding the research, an in-class discussion of the project goals will occur if deemed necessary.

7. Conflict of Interest

This is no conflict of interest or potential conflict of interest for the PIs.

8. HIPPA Compliance

This project does not use or seek access to PHI information.

9. Research Outside the US

Not applicable

10. Research Involving Prisoners

Not Applicable

Understanding Student Learning in CORE Undergraduate Science Courses

Participant Informed Consent Form

As a member of this class and program you are being asked to participate in a research project being conducted by Undergraduate Studies and the Center for Teaching Excellence at the University of Maryland College Park. The purpose of the research is to evaluate your science education experiences within the CORE undergraduate science courses. The procedures of this research will involve your participation in surveys and short writing responses which may be part of the normal class educational activities. Participation in the projects activities will in general requires less than 30 minutes. Participation in these activities is voluntary except in those cases where the activity is an embedded class activity. If you chose not to participate in this study your work will removed from the materials used in this study.

All information collected in this study is confidential and I understand I will not be identified by name, or other indicators of identify. **Unless I specifically agree (as indicated my response below) to have my name used where I am individually cited or quoted.**

I understand there is not foreseeable risk associated with participation in this research project. Your choice to participate or not will not effect your grade in the course.

I understand that I am free to ask questions or withdraw from participation in the project at any and without penalty. Questions regarding this research can be directed to the Principle Investigator, Dr. Spencer Benson, Director Center for Teaching Excellence; 301-314-1288, Email; sbenson@umd.edu

If you have questions about your rights as a research subject or wish to report a research-related injury, please contact: Institutional Review Board Office, University of Maryland, College Park, 20742: (email) irb@deans.umd.edu; (telephone) 301-314-4212.

- I, the participant, state that I am 18 year or age or older, and agree to participate in the research project being conducted by the Office of Undergraduate Studies and Center for Teaching Excellence at the University of Maryland College Park.
- I chose to **NOT** participate in this project
- I prefer to have specific quotes attributed to my name.

Name of Participant: Last _____ First _____

Signature _____

Date _____

Email Address _____

Phone Number _____