PROTOCOL NARRATIVE FOR EXEMPT RESEARCH

University of California, Irvine
Institutional Review Board
Version: January 2010

IMPORTANT TIME SAVER: THIS FORM SHOULD BE USED ONLY IF THE RESEARCH CAN BE CATEGORIZED AS EXEMPT RESEARCH.

TO VERIFY THAT THE PROPOSED RESEARCH MEETS ONE OF THE EXEMPTION CATEGORIES PLEASE REVIEW THE EXEMPT CATEGORY DESCRIPTIONS.

IF THE RESEARCH CANNOT BE CATEGORIZED AS EXEMPT, PLEASE COMPLETE THE PROTOCOL NARRATIVE FOR EXPEDITED/FULL COMMITTEE RESEARCH.

IMPORTANT: CAREFULLY READ THE INSTRUCTIONS FOR EACH SECTION BEFORE COMPLETING THE PROTOCOL NARRATIVE.

NEED HELP? CONTACT THE HRP STAFF FOR ASSISTANCE

HS#: 
For IRB Office Use Only

Lead Researcher Name: Dr. Diane K. O’Dowd
Study Title: Using Active Teaching to Enhance Student Performance and Satisfaction in Biology at UCI

NON-TECHNICAL SUMMARY

Provide a non-technical summary of the proposed research project. The summary should include a brief statement of the purpose of the research and a brief description of the procedure(s) involving human subjects. This summary should not exceed ¼ page.

Research faculty at large universities are facing increased pressure to use more active learning in their lecture courses. They are also being encouraged to explore online teaching. Our research goal is to develop teaching methods that will increase student learning and satisfaction in core biology courses, both onsite and online, that will be usable by research faculty who have limited time to completely invent or restructure courses. Our general procedure is to:

1. Teach multiple sections of core biology courses.
2. Use a crossover design where some students are taught using one new method and some are taught using a traditional method. These methods are then switched later in the course so that all students are given equal exposure.
3. Record student performance on biology concept inventory quizzes and normal course exams.
4. Gather student opinion on the course using the department issued course evaluations and anonymous surveys.
5. Follow student success through the core courses of biology by collecting their final grades from the registrar and scores on the biology concept inventory quizzes from faculty.
SECTION 1: PURPOSE OF THE RESEARCH

1. Describe the purpose of the research project and state the overall objectives, specific aims, hypotheses (or research question) and scientific or scholarly rationale for performing the study.

2. Clearly identify the primary outcome(s) and key factor(s) of interest, as applicable.

The first years of undergraduate core biology classes at UCI are traditionally taught using standard didactic lectures since each class typically has 300-400 students. This teaching style is geared toward transmission of facts, and students feel as if they have fully prepared for exams by reviewing the facts in the lecture notes and the textbook multiple times. But current neuroscience research indicates that true learning only occurs if students work through a multi-step process to incorporate new material into their pre-existing framework of biological knowledge (Lambert and McCombs, 1997; Driver et al., 1994). This process requires that students closely examine each concept, recognize what parts do not fit their pre-existing model of biology, seek to discover the source of the error (in the new concept or the pre-existing model), and work to find the correct information (Michael, 2006). Most students do not instinctively work through these steps with each concept they are given in lecture. One major difficulty is that students don’t manipulate the concept enough to realize they don’t understand it. They confidently enter the exam, only to discover that their biological framework is full of errors (Hacker et al., 2000; Dunning et al., 2004).

Utilization of active teaching techniques in large lectures has been shown to be effective for improving student learning and retention (Knight and Wood, 2005; Allen and Tanner, 2005; Caldwell, 2007) but many techniques are time consuming to develop and hinder the faculty member's progress in their research. In Bio 93 "DNA to Organisms" at UCI, we have successfully implemented several active teaching techniques with relatively low impact on the faculty member's time. The multiple sections of Bio 93 are ideal for testing the effectiveness of teaching techniques because they are taught by the same faculty teams. Thus, our research explores several aspects of helping research faculty teach more effectively and with increased student satisfaction and performance. Our current projects are:

Forums in Online Learning: A standard tool used in online courses is the forum, where students are expected to replace classroom peer-peer and peer-teacher interaction with online interaction. The literature, however, indicates this tool is rarely used successfully (Rourke and Kanuka, 2009). We are examining if forums can be made effective if students are given a difficult project to complete and are allowed to work together online. Key factor of interest: Does forum use in an online course increase student learning and student satisfaction?

Online vs. Onsite Student Performance: Multiple studies have shown that students who take a class online do about as well as their counterparts who take the class onsite, but that their performance is influenced by many factors (Merisots and Phipps, 1999; Bernard et al., 2004). UC Irvine has never had a biology core course offered both online and onsite. Because incoming freshmen represent a special demographic at UCI, we have offered to compare how well our students do when allowed to take Bio 93 online. Key factor of interest: do students who choose to take Bio 93 online do better in the online class than students who asked to take it online and were not allowed to?

Laptops in the Large Lecture Environment: Anecdotally, many faculty at UCI are concerned about the effects of laptop use (and misuse) on student performance and the overall atmosphere of the classroom. Only minimal data is available to guide faculty decisions about how to manage laptops in their lecture. Studies thus far suggest laptop note-takers perform worse than paper note-takers in small class sizes (Fried, 2008; Grace-Martin and Gay, 2001; Hembrooke and Gay, 2003), but data from large lecture halls
are lacking. We are interested in whether seating laptop users in one part of the lecture hall improves the concentration of non-laptop-users without negatively affecting the laptop users. Key factor of interest: does limiting laptop use improve student performance and student satisfaction with the course?

In-Situ Discussion Leader Training: Having graduate students teach discussion sections for very large biology classes gives the graduate students an opportunity to learn how to teach while maximizing active learning for the undergraduates in the course. We have developed a curriculum to help faculty train graduate students to teach, and we will continue to collect data on faculty and graduate student satisfaction with the program. Key factor of interest: does an active learning TA Training program prepare graduate students to teach successfully while they balance their research?

Self-affirmation exercises: Because Bio 93 is a “gateway” course for the major (~85% of the students are Freshmen Biology majors), performance in this class is a strong determinant of future success in the major. A Division of Bio Sci policy change in Fall 2010 has made performance in the class even more important for students as they are not allowed to continue in the core Bio sequence if they receive a grade below C- in this first course. Despite years of increasing use of active teaching techniques and formative assessment activities, as well as improved TA training for active discussion sections, women and underrepresented minorities (URMs) continue to underperform (unpublished data from UCI Office of Institutional Research). Similar issues have been observed on other campuses (Haak et al, 2011), and many are turning to interventions based on cognitive science to foster success in at-risk populations of undergraduates (Miyake et al, 2010; Scott Freeman pers comm., University of Washington).

One such intervention is the self-affirmation exercise (Cohen et al, 2000; Cohen et al 2006). In the face of a perceived threat, individuals can reaffirm their self-worth by affirming other equally valued domains of self-worth. The process of self-affirmation reduces stress (Cresswell et al, 2005), leading to improved performance (Sherman & Cohe, 2006). Self-affirmation exercises have been found to reduce gender gaps in performance in physics courses (Miyake et al, 2010; Kost-Smith et al, 2010), and it is most effective for women who endorse gender stereotypes (e.g. men are better at math than women).

Key factor of interest: Can a self-affirmation exercise reduce the performance gaps among women and URMs in Bio 93?

References:


SECTION 2: ROLES AND EXPERTISE OF THE STUDY TEAM

List all study team members below.

1. Identify each **member's position** (e.g., Associate Professor, graduate or undergraduate student) and **department**, and describe his or her **qualifications, level of training and expertise**. Include information about relevant licenses/medical privileges, as applicable.
2. Describe each team member's **specific role and responsibility** on the study.
3. **Faculty Sponsors** - list as Co-Researchers and describe their role on the project; include oversight responsibilities for the research study.
4. Explain who will have **access to subject identifiable data**.
5. Indicate who will be **involved in recruitment, informed consent process, research procedures/interventions, and analysis of data**.

**Lead Researcher:**
Dr. Diane O'Dowd is a Howard Hughes Medical Institute Professor who is working on multiple initiatives to improve undergraduate education in research institutions. She is actively pursuing mechanisms to allow faculty to teach more interactively and with greater satisfaction in large lecture halls. She designed the study and will be involved in both training the students and in analyzing data after student identifiers are removed, and in writing and publication of the results. She will also be a member of the Bio 93 teaching team.

**Co-Researcher(s):**
Dr. Adrienne Williams is the Co-Director of the HHMI Professor program for Dr. Diane O’Dowd. Her responsibilities include organizing background information, study design, IRB narrative submission, and is responsible for making sure that each study is carried out correctly. She will serve as the contact person for the students.

Dr. Nancy Aguilar-Roca is a project specialist in Developmental and Cell Biology who will be the course coordinator for Bio 93 sections A and B. She will be involved in overseeing collection and analysis of data and preparation of publications after student identifiers have been removed.

**Research Personnel:**
Experiment 1 (Forums in Online Learning): Dr. Marin Moravec is a project specialist in Developmental and Cell Biology who will aid the Lead and Co-Researchers in gathering the data, analyzing it and preparing the publications.

Experiment 2 (Online vs Onsite): Dr. Marin Moravec is a project specialist in Developmental and Cell Biology who will aid the Lead and Co-Researchers in gathering the data, analyzing it and preparing the publications. Dr. Rahul Warrior is a faculty member in Developmental and Cell Biology and he will co-teach Bio 93 sections A and B with Dr. O'Dowd.
Experiment 3 (Laptop Use): Several faculty members will be assisting with the data collection in their classes: Dr. Rahul Warrior is a faculty member in Developmental and Cell Biology and he will co-teach Bio 93 sections A and B with Dr. O’Dowd. Dr. Marcelo Wood and Dr. Jorge Busciglio are faculty members in Neurobiology and Behavior and they will co-teach Bio 93 sections C and D. Dr. Lawrence Cahill is a faculty member in Neurobiology and Behavior and he will teach Bio N158.

Experiment 4 (In-Situ TA Training): no additional research personnel will be used.

IMPORTANT TIME SAVER: If requesting Exempt Registration under Category 4 ONLY, complete the non-technical summary, Sections 1-2 and Sections 10-11.

SECTION 3: EXEMPT CATEGORY JUSTIFICATION

If you are requesting Exempt Registration per Category(ies) 1-3 or 5, provide a brief justification for why the research meets each applicable Exempt category.

Note: Research involving prisoners is not eligible for Exempt Registration. Also, research involving children may only be Exempt under Category 1; or under Category 2 if the research involves only educational tests or observation without direct interaction by the researchers.

Our research meets the “Exempt” requirement because it matches Category #1b: 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 of or the comparison among instructional techniques, curricula or classroom management methods.

SECTION 4: RESEARCH METHODOLOGY/STUDY PROCEDURES FOR EXEMPTION

A. Study Design and Procedures

1. Provide a detailed chronological description of all study activities (e.g., pilot testing, recruitment, screening, intervention/interaction/data collection, and follow-up) and procedures.
   a. Indicate how much time will be required of the subjects, per visit and in total for the study.
   b. Indicate the setting where each procedure will take place/be administered (e.g. via telephone, sent via email, online, classroom). Note: If any of the procedures will take place at off-campus location (e.g., educational institutions, businesses, organizations, etc) Letters of Permission are required.
   c. If a procedure will be completed more than once (e.g., pre and post survey), indicate how many times and the time span between administrations.

2. If study procedures include collecting photographs, or audio/video recording, specify whether any subject identifiable will be collected and describe which identifiers will, if any.

3. Describe how the subject’s privacy will be protected during the research procedures. Note: This is not the same as confidentiality (see the Privacy and Confidentiality web page).

4. Be sure to submit data collection instruments for review with your e-IRB Application (e.g.,
measures, questionnaires, interview questions, observational tool, etc.). **Note: If the instrument is still being developed, submit a draft with this application. The final version of the data collection instrument must be submitted to the IRB via an eMOD request before you begin data collection.**

All of our research fits our general goal of enhancing student performance at UCI, but each project differs in methodology. The specific aspects of each project are given below.

**Experiment 1: Forums in Online Learning**

**Recruitment of study participants:**
1. Students will enroll normally into the summer 2010 online Bio 93.
2. Distance Learning will randomly assign the students (up to 180 total) into one of two online copies of the class.
3. The introductory packet will describe our use of student records and will contain a student courtesy letter (see Experiment 1 Packet). Students who do not wish their records to be used or who are under 18 will be asked to contact Dr. Williams to opt out.

**Course Delivery**
1. Both courses will be taught by Diane O’Dowd
2. Both classes will have equivalent course content and assignments.
3. In the “Forum” class, the students will complete a weekly assignment to make a visual demonstration of a biological concept using an online forum to help guide their understanding. Students will work in groups online to present the best demo of the group to the course instructor for her approval.
4. Students in the “Non-Forum” class will submit the same assignment and receive credit, but not have forums or groups to discuss the project with.

**Data Collected from Class Materials:**
1. Students will be given a 27-question biology concept inventory quiz at the start and end of the class to assess incoming biology knowledge. This online, multiple-choice quiz will take approximately 30 minutes to complete and is a normal part of the course.
2. Students will be given the same quizzes and exams at the same times in both courses. These exams are the standard instruments developed and used in the course.
3. Both classes will receive the standard course evaluation at the end of the class. This is administered online, takes approximately 10 minutes to complete, and is a normal part of the course.

**Data Collected from Research Surveys:**
1. Both classes will be asked to fill out an online survey asking about their satisfaction with the course (see Experiment 1 packet). This survey will take about 10 minutes to complete, and be anonymous and optional. Consent will be obtained using a Study Information Sheet at the beginning of the survey (see Experiment 1 packet).

**Data Collected from Registrar:**
1. After final student grades have been submitted, we will ask the registrar for student-specific data for the course: gender, ethnicity, SAT scores, and class level. This information will be matched to the students in the class in our database, which will also contain their class scores and survey results.

**Data Storage**
1. The student names and IDs will be removed from all class materials, research instruments, and student records and replaced with a random ID, and the conversion file will be removed from analysis computers and stored separately.
Analysis:
1. Compare between the two experimental groups:
   a. Performance on exams, particularly questions related to the forum projects.
   b. Percent change in pre to postclass concept inventory test
   c. Precourse academic indicators: SAT scores, preclass concept inventory test
   d. Overall satisfaction with course
   e. Overall satisfaction with instructor
   f. Overall satisfaction with peer interaction

Experiment 2: Online vs. Onsite Class Performance

Recruitment of study participants
1. Students will enroll normally in the onsite Bio93 Sections A and B through September 15, 2010 (incoming freshman enrollment begins Sept 1st).
2. On September 15, an email will be sent out to all students enrolled in Bio 93 Section B. They will be told that an online version of the course is being offered and asked to indicate, yes they want to be enrolled in the online class or no they don’t want to be enrolled in the online class (see Experiment 2 packet).
3. On September 21, the students indicating they want an online class will be randomly sorted into two groups. The maximum enrollment for the online course will be 50 students.
4. Four experimental Groups
   a. Group A: up to 50 will be enrolled in online class
   b. Group B: of online requesters will be left in onsite class
   c. Group C: Students who elect to stay onsite
   d. Group D: Students who fail to respond to email in indicated time window
5. In the online class, the introductory packet will describe our use of student records and will contain a student courtesy letter (see Experiment 2 Packet). In the onsite class, Dr. Williams will present the research on the first day of class, and the courtesy letter will be posted on the class website. Students who do not wish their records to be used or who are under 18 will be asked to contact Dr. Williams to opt out.

Course Delivery:
1. Both onsite and online courses will begin on the first day of Fall quarter and will take place over the 10 week duration.
   a. O’Dowd and Warrior will team teach the onsite class for Section A and B. Each lecture includes ~30 minutes of content delivery and ~20 minutes of active learning. Direct interaction with Dr. O’Dowd and Warrior will occur during office hours. TAs will handle online forums where students can ask content questions. Dr. O’Dowd will participate in forums to a small degree.
   b. Dr. O’Dowd will teach the online course. Students will cover the same content as the onsite course. The content will be delivered via worksheets, animations, links to YouTube videos, and student-built “demonstrations.” Direct interaction with Dr. O’Dowd will occur during onsite office hours. TAs will handle online forums where students can ask content questions. Dr. O’Dowd will participate in forums to a small degree.
2. Both the onsite and online classes will have two course quizzes, an onsite midterm and an onsite final exam. The online course will have their quizzes, midterm and final at the same times as the Lecture B section (in a different room), and will take the same exams.
3. Both the onsite and online class will have 80% of their final grade based on the quizzes, midterm and final, and 20% based on participation in various activities. The onsite class will have online mini-quizzes, clicker participation, LBL homework assignments, and discussion activities. The online class will have online mini-quizzes, worksheet assignments, forum participation, and
demonstration projects.
4. All TAs and faculty involved in the online course will monitor their hours spent on the course.

Data Collected from Class Materials:
1. Students will be given the same quizzes and exams at the same times in both courses and answer choices for all exam elements will be recorded for each student.
2. The onsite and online classes will be given the same standard teaching evaluation form at the end of the quarter. These are anonymous and administrated by the University.
3. Hours spent by online course instructor and TAs will be recorded.
4. Online student access to elements of the online course will be collected (as recorded by Moodle). Student names will be replaced with random IDs and the records of access stored in a database.

Data Collected from Research Surveys:
1. All students in Lecture B will be sent an EEE survey before the first day of class, asking why they were or were not interested in the online class (see Experiment 2 packet). The survey is online and will take approximately 5 minutes to complete. Student responses will be anonymous and optional. Consent will be obtained using a Study Information Sheet at the beginning of the survey (see Experiment 2 packet).
2. Both classes will receive EEE surveys after the end of the quarter, and will be asked about the course (see Experiment 2 packet). These surveys will be administered electronically and will take about 10 m to complete. Participation is anonymous and optional. Consent will be obtained as above.

Data Collected from Registrar:
1. After final student grades have been submitted, we will ask the registrar for student-specific data for the course: gender, ethnicity, SAT scores, and class level. This information will be matched to the students in the class in our database, which will also contain their forum activity and their exam and quiz scores.
2. Enrollment of students in each of the four groups will be retrieved from the Registrar in Bio 94 (Winter 2011) and Bio 97 (Fall 2011).
3. Enrollment and performance of students in each of the four groups will be followed as they progress through the core classes of the biology major (Bio 94, 97, 98, 99). Student grades in those classes will be collected from the Registrar.

Data Storage:
1. The student names and IDs will be removed from all class materials, research instruments, and student records and replaced with a random ID. The conversion file will be removed from analysis computers and stored separately.

Analysis
1. Compare between the four experimental groups:
   a. Performance on exams
   b. Percent change in pre to postclass concept inventory quiz
   c. Precourse academic indicators
      i. SAT scores, preclass concept inventory quiz
   d. Overall satisfaction with course, instructor, and peer interaction
   e. Response to whether there should continue to be an online as well as onsite course option
2. Are there differences between the experimental groups in the probability that students will continue in the biology core? Follow enrollments and performance of these students in Bio 94, 97, 98 and 99.
Experiment 3: Laptops in the Large Lecture Environment

Recruitment of study participants:
1. Students will enroll normally into the Fall 2010 sections Bio 93: A, B, C and D, and Bio N158 (Neurobiology of Learning and Memory).
2. Attendees at the annual conference of the Society for the Advancement of Biology Education Research (SABER; University of Minnesota East Campus; July 29-31, 2011) will be asked to fill-out a survey regarding their laptop-use policies at their home institutions.

Course Delivery
1. Bio 93A: Dr. O’Dowd will announce that laptop users will need to sit on the left side of the lecture hall. She will show previous class data that demonstrate students who use laptops do not perform as well in the class as those who take notes by hand.
2. Bio 93B: Dr. O’Dowd will allow laptop use without comment.
3. Bio 93C: Dr. Wood and Busciglio will announce that laptop users will need to sit on the left side of the lecture hall. They will show previous class data that demonstrate students who use laptops do not perform as well in the class as those who take notes by hand.
4. Bio 93D: Dr. Wood and Busciglio will allow laptop use without comment.
5. Bio N158 (Neuro Bio Learn Mem): Dr. Cahill will announce that laptop users will need to sit on the left side of the lecture hall. He will show previous class data that demonstrate students who use laptops do not perform as well in the class as those who take notes by hand.
6. For all courses, the content will not be altered.

Data Collected from Class Materials:
1. Students enrolled in all sections of Bio 93 will be given a 27-question biology concept inventory quiz at the start and end of the class to assess incoming biology knowledge. This online, multiple-choice quiz will take approximately 30 minutes to complete and is a normal part of the course.
2. Students in Bio 93 sections A and B will be given the same quizzes and exams at the same times. These exams are the standard instruments developed and used in the course.
3. Students in Bio 93 sections C and D will be given the same quizzes and exams at the same times. These exams are the standard instruments developed and used in the course.
4. Students in Bio N158 be given quizzes and exams that are the standard instruments developed and used in the course.
5. All classes given a midterm and final exam as a normal part of the course. It is common practice to include an optional opinion question, worth zero points. A multiple choice question regarding note taking practices will be included on both exams to track changes in student note taking during the quarter (see Experiment 3 packet).
6. All classes will receive the standard course evaluation at the end of the class. This is administered online, takes approximately 10 minutes to complete, and is a normal part of all Bio Sci courses.

Data Collected from Research Surveys:
1. All classes will be asked to fill out an online survey asking about their satisfaction with the course (see Experiment 3 packet). This survey will take about 10 minutes to complete, and be anonymous and optional. Consent will be obtained using a Study Information Sheet at the beginning of the survey (see Experiment 3 packet).
2. A member of our research team (Dr. Aguilar-Roca) will be presenting data at the annual SABER conference. Faculty attending her talk will be asked to participate in an active learning activity and fill-out a one-page anonymous survey related to laptop use during her 30-min presentation. The activity will consist of attendees turning-in a colored index card in response to the following PowerPoint slide:

Please turn-in the color of index card that matches your response to this
question
What percentage of the time do you think student laptop users are off-task?
White = 0 – 30%
Green = 30 – 60%
Blue = > 60%

The one-page survey is attached. Consent will be obtained using a Study Information Sheet that will be attached to the survey.

Data Collected from Registrar:
1. After final student grades have been submitted, we will ask the registrar for student-specific data for the course: gender, ethnicity, major and class level. This information will be matched to the students in the class in our database, which will also contain whether or not they were in a section with unregulated laptop use, or in a section with separated laptop users.

Data Storage
1. The student names and IDs will be removed from all class materials, research instruments, and student records and replaced with a random ID, and the conversion file will be removed from analysis computers and stored separately.

Analysis:
1. Comparisons will be made using:
   a. Aggregate performance data of sections with unregulated laptop use and sections with separated laptop use.
   b. Performance on exams of students who did or did not use a laptop in the sections with or without laptop regulations.
   c. Percent change in pre to postclass concept inventory test for laptop users versus non-laptop users in the sections with or without laptop regulations.
   d. Overall perceptions of the effect of laptop use on the classroom environment in the sections with or without laptop regulations.
   e. Potential cultural influences on laptop use based on gender, ethnicity, major and class level.
   f. Aggregate data from the SABER conference survey will be used to assess laptop management opinions and strategies currently utilized in other undergraduate biology courses, as well as the potential broader impacts of this study.

Activity 4: In-Situ Discussion Leader Training
Enrollment of study participants:
1. We accept all grad students who have been asked to teach Bio 93 or Bio 97 and whose course instructors have agreed to work with us.
2. Students who wish to become “HHMI-UCI Fellows” enroll in an optional 1-unit course called “Balancing the Academic Workload.” They agree to be surveyed about their experience, and agree to allow their teaching evaluations to be used for the class evaluations.

Assessment:
1. Teaching evaluations are submitted by the Mentor TA of their class and by the faculty instructor of the class.
2. Student evaluations at the end of the quarter are submitted by the departments of record.
3. TAs submit a pre-quarter and an end-of-the-quarter evaluation of the training that is anonymous and asks:
   a. Amount of pre-training teaching experience
   b. Course they TAed for
   c. Value of the teaching training, including ranking the activities
   d. Suggestions to improve the training
4. Students are contacted every other year for the next four years and asked:
   a. What teaching have you done since the TA training?
   b. What long-term effect did the training have on your teaching and on your ability to balance teaching and research?
   c. Would you recommend other graduate students complete the training?

Analysis:
1. Record and publish aggregate data about:
   a. Number of students who have completed the training
   b. Number in teaching professions
   c. Number who feel the training was useful
   d. Sample comments from surveys about the activities and training
2. Create a Manual that contains activities created by graduate student TAs.

Activity 5: Self-affirmation exercise to reduce performance gaps

Enrollment of study participants:
Students will enroll normally into the Fall 2011 sections of Bio 93 A, B, C, D and E

Course Delivery
1. Sections A and B will be taught by Dr. Diane O’Dowd and Dr. Rahul Warrior. Sections C, D and E will be taught by Dr.'s Marcelo Wood and Jorge Busciglio. A member of the research team who does not teach the course will explain how to opt out of the study on the first day of class in each section.

2. Both classes will have equivalent course content, assignments and exams.

3. The in-class self-affirmation exercise will be given to Section A of Bio 93 (~440 students). On the second day of lecture, students will receive the 3-page packet during lecture. Half of the students will receive a control packet and half will receive an affirmation packet. Students will have ~15 minutes to complete the exercise and then pass in their packets. A member of our research team (who is not affiliated with teaching the course) will distribute and collect the packets, and the faculty instructor will not be involved with distributing or collecting the packets. The self-affirmation and control packets are attached as separate documents.

4. The self-affirmation exercise in Section B of Bio 93 (~440 students) will be conducted entirely online via the EEE survey tool. Students will be randomly selected to receive either the affirmation or control assignment in an online format through EEE. The online version self-affirmation and control will be identical to the in-class version. A member of our research team will set-up the assignment so that it is not directly associated with the faculty instructors. Students will be told that their responses are confidential and that they will have 15 minutes to complete the assignment. The online assignment will be available on the same day that Section A receives their packets. When the assignment is announced in class, students will be reminded of how to opt-out of the study.
5. In both sections, students will be told that this assignment is a writing exercise to assess their communication skills. Prior research has shown that informing people that this exercise will improve their performance actually reduces the effectiveness of the exercise (Sherman et al, 2009).

6. Prior to the first midterm exam, students in both sections will complete the exercise again online. A member of our research team will determine which students completed the control versus the affirmation the first time and assign the second online exercise accordingly.

7. In the event that there is a significant effect of the intervention, the control and affirmation students will be graded on separate curves to ensure fair assignment of grades within each section.

Data Collected from Class Materials:

1. Students enrolled in all sections of Bio 93 will be given a 27-question biology concept inventory quiz at the start and end of the class to assess incoming biology knowledge. This online, multiple-choice quiz will take approximately 30 minutes to complete and is a normal part of the course.

2. Students in Bio 93 sections A and B will be given the same quizzes and exams at the same times. These exams are the standard instruments developed and used in the course.

3. All classes will receive the standard course evaluation at the end of the class. This is administered online, takes approximately 10 minutes to complete, and is a normal part of all Bio Sci courses.

Data Collected from Research Surveys:

In order to assess the degree to which each student endorses a gender or URM stereotype, an attitude survey will be given during discussion sections in the final week of the course. Two questions that assess stereotype endorsement for each area will be embedded in a larger survey of student attitudes towards learning. The questions selected for this survey have been validated in other studies and have had a consistent correlation with student performance. The survey questions can be grouped into 5 broad categories (below). The survey data will be used to determine if there are other variables that can be used to identify at-risk students in future courses. It will be given to discussion sections for all 5 Bio 93 lecture sections in order to validate the consistency of the survey questions across all Bio 93 students and faculty.

1) Self-efficacy for Learning and Performance is a self-appraisal of one’s ability to master a task. All of the questions in this subscale are from the Manual for the Use of the Motivated Strategies for Learning Questionnaire (MSLQ; Pintrich, 1991). This subscale has consistently shown a strong correlation with final class grades across multiple disciplines and cultures.

2) Metacognitive self-regulation is the use of self-regulatory activities for planning (e.g. goal setting), monitoring (e.g. self testing) and regulating (adjustment of one’s cognitive activities). Half of the questions in this subscale are from the MSLQ and half are from the Colorado Learning Attitudes about Science Survey (CLASS). Other studies have suggested that it is preferable to use items that are as specific as possible to the course. Items from the CLASS were chosen for their equivalence with items from the MSLQ and specificity to biology.

3) Task Value is the student’s perception of the course material in terms of interest, importance
and utility. All items in this subscale all are from the CLASS to make it specific to biology.

4) Help-seeking is an a students ability to manage the support of others, including peers and instructors. Good students know when they don’t know something and are able to identify someone to provide them with some assistance. Both items in this subscale are from the MSLQ (Pintrich, 1991).

5) Stereotype threat is the perception that anything one does, or any of one's features, conform to a negative stereotype. Thus making the negative stereotype more plausible in the eyes of others, and perhaps even in one's own eyes Spencer et al (1999). Questions for this subscale are from Miyake et al (2010) and Spencer et al (1999).

The survey will be worth 1 discussion point. Students will be told that completing the survey is voluntary, but that they must turn-in their name in order to receive their point. The informed consent letter will be printed on the back of the survey when it is distributed to the students in discussion section (document attached).

**Data Collected from Registrar:**
After final student grades have been submitted, we will ask the registrar for student-specific data for the course: gender, ethnicity, major, year of matriculation into UCI, SAT (math and verbal) and AP Biology. This information will be matched to the students in the class in our database, which will also contain whether or not they received the control or self-affirmation exercise, as well as their survey responses.

**Data Storage**
The student names and IDs will be removed from all class materials, research instruments, and student records and replaced with a random ID, and the conversion file will be removed from analysis computers and stored separately.

**Data Analysis**
Comparisons will be made using:

a. Aggregate performance data of students who completed the control versus the affirmation exercise.

b. Percent change in pre- to post-class concept inventory test for students who completed the control versus the self-affirmation exercise.

c. Potential influence of attitude and stereotype threat on changes in exam performance with or without a self-affirmation exercise.

**IMPORTANT TIME SAVER:** Complete Part B ONLY if you are requesting permission to review student academic records.

1. **Student Academic Records Review**
1. Specify the **types/source of records/data** that will be reviewed by selecting the appropriate bracket(s) below.

2. If you will **manually extract research** data from academic records, upload a Data Extraction Sheet when you submit your e-IRB application (i.e. the document used to record the information). **Note:** The application will be considered incomplete until this is submitted.

   [ ] School Records (specify): student-specific data from Registrar (see individual experiments, below)
   [ ] Individual level data from an established data repository (specify):
   [ ] Other (specify):

3. Specify how the **records/data will be obtained**, and whether the data are **publicly available**.

4. Submit a copy of the **School or School District Permission Letter** to access the academic records with your e-IRB Application. **Note:** Since official student records will be accessed for research purposes, the letter of permission must address how Title 34 of the Code of Federal Regulations Part 99 - Family Educational Rights and Privacy Act (FERPA) applies to this research.

Experiment 1: Collected from Registrar: gender, ethnicity, SAT scores, and class level.
Experiment 2: Collected from Registrar: gender, ethnicity, SAT scores, and class level.
Experiment 3: Collected from Registrar: gender, ethnicity, SAT scores, and class level.
Experiment 4: Not relevant
Experiment 5: Collected from Registrar: gender, ethnicity, major, SAT scores (math & verbal), AP Biology scores, and year of matriculation into UCI.

5. Specify how the **data are identified** when they are made available to the study team. Please indicate by marking the appropriate bracket(s) below.

   i) [ ] No Identifier (i.e., neither the researcher nor the source providing the data can identify a student based upon information provided with the data)
   ii) [ ] Indirect Identifier* (i.e., an assigned code will be kept which could be used by the investigator or the source providing data to identify a student, such as a tracking code used by the source.)
   iii) [X] Direct Identifier (i.e., student name, address, social security number, academic record number, etc. will be attached to data)

   *If ii is checked above, specify whether the study team will be given access to the code.

   [ ] Yes, the study team will have access to the link between the tracking code and subject identities.
No, the study team will not have access to the link between the code and subject identities.

SECTION 5: SUBJECTS

A. Number of Subjects

1. Indicate the maximum number of subjects to be recruited/consented on this UCI protocol. This is the number of potential subjects you may recruit in order to get your sample—not just the number who actually participate in the study.
2. For studies where multiple groups of subjects will be evaluated, please provide a breakdown per group (e.g., controls vs. experimental subjects; children vs. adults).
3. For Mail/Internet surveys include the number of people directly solicited.
4. For academic records review, specify the maximum number of records that will be reviewed to compile the data necessary to address the research question or the maximum number of individuals that will comprise the dataset.

Experiment 1: Summer session: 120–200 students, Fall Bio 93: 1700 – 2000 students
Experiment 2: Fall Bio 93 online: 50, Fall Bio 93 onsite Sections A, and B: approx. 800 students
Experiment 3: Students in Fall Bio 93 Sections A, B, C, D and Bio N158: approx. 2000 students
Experiment 3: Approximately 60 participants from the SABER Conference
Experiment 4: 10–30 current graduate students, up to 100 past participants
Experiment 5: Students in Fall Bio 93 Sections A, B, C, D and E: approx. 2000 students

Max Total: 7180

B. Subject Populations

1. Describe the characteristics of the proposed subject population. At a minimum include information about the age and gender of the study population.
2. Describe different subject groups (e.g., students and teachers) separately.

Experiment 1: Students will be UCI undergraduates who enroll in Bio 93. Most are incoming freshmen around 18 years old, around 60% female. Students under the age of 18 on the first day of class will be automatically excluded.
Experiment 2: Students will be UCI undergraduates who enroll in Bio 93. Most are incoming freshmen around 18 years old, around 60% female. Students under the age of 18 on the first day of class will be automatically excluded.
Experiment 3: Students will be UCI undergraduates who enroll in Bio 93 and Bio N158. Most Bio 93 students are incoming freshmen around 18 years old, around 60% female. Most Bio N158 students are upperclassmen, ~60% female. Students under the age of 18 on the first day of class will be automatically excluded.
Experiment 3: SABER Conference attendees will be faculty members who teach biological sciences at a diversity of institutions throughout the US.
Experiment 4: Graduate students are about 50% male and 50% female. Average age is early 20s.
Experiment 5: Students will be UCI undergraduates who enroll in Bio 93. Most are incoming freshmen around 18 years old, around 60% female. Students under the age of 18 on the first day of class will be automatically excluded.
around 18 years old, around 60% female. Students under the age of 18 on the first day of class will be automatically excluded.

### SECTION 6: RECRUITMENT METHODS AND PROCESS

#### A. Recruitment Methods

Please check all applicable recruitment methods that apply to the study. Place an “X” in the bracket [   ] next to the recruitment method.

| [ ] UCI IRB approved advertisements, flyers, notices, and/or media will be used to recruit subjects. **Submit advertisements for IRB approval.**  
|   |   | Passive Recruitment - Potential subjects initiate contact with the study team.  
|   |   | **Complete Question 6B - Explain where recruitment materials will be posted.**  
| [X ] The study team will recruit potential subjects who are unknown to them (e.g., convenience sampling, use of social networks, direct approach in public situations, random digit dialing, etc.)  
|   |   | Active Recruitment – Researchers contact potential subjects.  
|   |   | **Complete Question 6B.**  
| [ ] The UCI Social Sciences human subject pool will be used. **Submit the Social Science Human Subject Pool Recruitment Advertisement for IRB approval.**  
|   |   | Passive Recruitment - Potential subjects initiate contact with the study team.  
|   |   | **Skip to Section 7.**  
| [ ] Study team members will contact potential subjects who have provided permission to be contacted for participation in future research studies.  
|   |   | Active Recruitment – Researchers contact potential subjects.  
|   |   | **Complete Question 6B – Explain when and how these individuals granted permission for future contact; provide the IRB protocol numbers, if applicable.**  
| [X ] Study team members will approach their own patients, students, employees for participation in the study.  
|   |   | Active Recruitment – Researchers contact potential subjects.  
|   |   | **Complete Question 6B.**  
| [ ] Other Methods:  
|   |   | **Complete Question 6B.**  


B. Recruitment Process

1. Based on the methods checked above, describe and provide details of the recruitment process (i.e. when, where, by whom and how potential subjects will be approached).

2. If you will recruit by mail, e-mail, or phone, explain how potential subjects’ contact information will be obtained.

3. If active recruitment methods will be used, explain how the individual’s privacy will be protected. Note: This is not the same as confidentiality (see the Privacy and Confidentiality web page).

Experiment 1: Students enrolled in the courses will automatically be included in the study. During the first lecture, someone other than the instructor will distribute a Study Information Sheet and explain that all data will be analyzed only after specific student identifiers have been removed, and that all data will be presented as aggregate means. They will also be told how to opt out of having their data used. It will be emphasized that their grade will not be affected by their choice, and that the data will not be analyzed until after the final grades are submitted. All of this information will also be posted on the course website. The online course has no first lecture, so the information will be posted as a letter on the class website.

Experiment 2: Students enrolled in the courses will automatically be included in the study. During the first lecture of the onsite course, someone other than the instructor will distribute a Study Information Sheet and explain that all data will be analyzed only after specific student identifiers have been removed, and that all data will be presented as aggregate means. An equivalent message will be delivered by the same person electronically to the online students. They will also be told how to opt out of having their data used. It will be emphasized that their grade will not be affected by their choice, and that the data will not be analyzed until after the final grades are submitted. All of this information will also be posted on the course website. After the class has ended and the next quarter is in progress, all students will receive an email from Dr. Aguilar-Roca that contains a pdf attachment of the Student Courtesy Letter (see Experiment 3 Packet). Students will be told they can opt out of the data supplied by the registrar by replying to the email (see Experiment 3 Packet for the email text).

Experiment 3: Students enrolled in the courses will automatically be included in the study. During the first lecture, someone other than the instructor will distribute a Study Information Sheet and explain that all data will be analyzed only after specific student identifiers have been removed, and that all data will be presented as aggregate means. They will also be told how to opt out of having their data used. It will be emphasized that their grade will not be affected by their choice, and that the data will not be analyzed until after the final grades are submitted. All of this information will also be posted on the course website. After the class has ended and the next quarter is in progress, all students will receive an email from Dr. Aguilar-Roca that contains a pdf attachment of the Student Courtesy Letter (see Experiment 3 Packet). Students will be told they can opt out of the data supplied by the registrar by replying to the email (see Experiment 3 Packet for the email text).

The survey and attached Study Information Sheet will be passed out to attendees at the conference presentation. Attendees will also be verbally informed that participation is anonymous and voluntary.

Experiment 4:
Graduate students will be consented using a Study Information Sheet prior to beginning participation in surveys or evaluations.
Experiment 5: Students enrolled in the courses will automatically be included in the study. During the first lecture, someone other than the instructor will distribute a Study Information Sheet and explain that all data will be analyzed only after specific student identifiers have been removed, and that all data will be presented as aggregate means. They will also be told how to opt out of having their data used. It will be emphasized that their grade will not be affected by their choice, and that the data will not be analyzed until after the final grades are submitted. All of this information will also be posted on the course website.

SECTION 7: INFORMED CONSENT PROCESS

1. If there will be contact with subjects*, then specify how consent will be obtained and describe the specific steps for obtaining informed consent (e.g. a study information sheet used to obtain verbal consent, an introductory paragraph included on the data collection instrument, a telephone script used, etc.).

2. Include information about when and where consent will take place and the length of time subjects will be given to decide whether they wish to participate.

3. If study team members will approach their own patients, students, or employees for participation in the study, then explain what precautions will be taken to minimize potential undue influence or coercion, and how compromised objectivity will be avoided.

4. If children are involved in this study, please describe the parental permission process and the child assent process.

5. Be sure to submit the consent/assent document(s) with your e-IRB Application.

6. If this study involves the creation, use, or disclosure of Protected Health Information (PHI), specify the process for obtaining HIPAA Authorization.

Check all that apply:

[ X ] N/A – There will be no direct subject contact. No consent process will take place. Explain why consent is not required.

[ X ] Written (signed) consent will not be obtained - Informed consent, parental permission and/or child assent will be obtained from subjects, as applicable. Explain how this will be obtained.

[ ] Written (signed) informed consent will be obtained – Signed informed consent, parental permission, and/or assent will be obtained from subjects, as applicable. Describe the informed consent process. Note: Signed informed consent is infrequently required when conducting Exempt research.

Experiment 1, 2 and 3: The UCI FERPA Analyst has approved a waiver of consent for the collection of student data from course work, as well as collection of demographic and longitudinal performance data from the Registrar. Students will be presented with a Courtesy Letter at the beginning of each course after the conclusion of each course that will explain this data collection process and give them an opportunity to redact their data for research if so desired.
Experiment 1: Consent for research instruments will be obtained at the beginning of each survey. Students can choose to not fill out the survey without their grade being affected.

Experiment 2: Consent for research instruments will be obtained at the beginning of each survey. Students can choose to not fill out the survey without their grade being affected.

Experiment 3: Consent for research instruments will be obtained at the beginning of each survey. Students can choose to not fill out the survey without their grade being affected.

Experiment 4: Consent for research instruments will be obtained at the beginning of each survey. Students can choose to not fill out the survey without their grade being affected.

Experiment 5: Consent for research instruments will be obtained at the beginning of each survey. Students can choose to not fill out the survey without their grade being affected.

7. **Non-English Speaking Participants:** In order to consent subjects who are unable to read and speak English, the English version of the consent form must be translated into appropriate languages once IRB approval is granted.

Check all that apply:

[X] Not applicable - Only individuals who can read and speak English are eligible for this study.

[ ] The English version of the consent form will be translated into appropriate languages for non-English speaking subjects once IRB approval is granted. An interpreter will be involved in the consenting process. **Note:** The IRB must officially stamp the translated consent forms.

**SECTION 8: PARTICIPANT COMPENSATION**

1. If subjects will be compensated for their participation, provide detailed information about the **amount and the method/terms of payment** (e.g., money; check; extra credit; gift certificate).

2. Describe the **schedule of compensation** (e.g., at end of study; after each session/visit).

**Note:** Compensation should be offered on a prorated basis when the research involves multiple sessions.

[X] No compensation will be provided to subjects.

**SECTION 9: CONFIDENTIALITY OF RESEARCH DATA**

1. Explain how the collected data will be identified.
[ ] No subject identifiers are obtained.
[ X ] Names and other subject identifying information are obtained but are not shared with anyone except the study staff.
[ ] Names and other subject identifying information are obtained and potentially used in publications/presentations. **Note: This may require written consent.**
[ ] Other (specify):

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2. Explain the manner in which the **data will be stored**.

**Note:** *If the research data includes subject identifiable information the storage devices or research files must be encrypted. Avoid storing subject identifiable data on portable devices (such as laptop computers, digital cameras, portable hard drives including flash drives, USB memory sticks, iPods or similar storage devices) as these devices are particularly susceptible to loss or theft.*

[X] Anonymous or de-identified data only (i.e., no code key)
[ ] Coded data with the code key kept in separate location. Key destroyed upon completion of the research or (specify):
[ X ] Coded data with the code key kept in separate location. Key maintained beyond the completion of the research.
[ ] Data includes subject identifiable information. **Note:** *If electronic record/file, encryption software is required.*

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3. **Explain how long subject identifiable research data will be retained.** The data may include a code with a separate code key or the data may include subject identifiers (hard copy documents, computer files, recordings, biospecimens)

[ ] Not applicable – No subject identifiers will be collected.
[ ] Research records will be retained for seven years after all children enrolled in the study reach the age of majority [age 18 in California] as this study includes children.
[ ] Destroy once data collection is completed
[ ] Destroy after publication/presentation
[ ] Maintain indefinitely for future research
[ X ] Maintain for future research (specify time frame, e.g., 3 months, etc.): Four years
[ ] Other (specify):

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4. If audio or video recordings will be collected, specify the **timeframe for the transcription and/or destruction of the audio and video recordings.**

5. If photographs will be collected, specify the **timeframe destruction of photographs**

[X] Not applicable – No audio/video recordings or photographs will be collected.
[ ] Audio or video recordings transcribed; specify time frame:
[ ] Audio or video recordings destroyed; specify time frame:
[ ] Audio or video recordings maintained indefinitely
[ ] Photographs destroyed; specify time frame:
[ ] Photographs maintained indefinitely
IMPORTANT TIME SAVER: ONLY COMPLETE Sections 10-11 if you are requesting Exempt Registration under Category 4. OTHERWISE STOP, YOU HAVE COMPLETED THE PROTOCOL NARRATIVE.

Note: If you will not have access to subject identifiers or the code key that links ID numbers and subject identifiers, this activity may not constitute human subjects research. You should submit a request for Determination of Non-Human Subjects Research.

SECTION 10: BIOSPECIMENS/CHARTS/RECORDS/DATASETS

A. Exempt Category 4 Eligibility

1. Will investigators have interaction or intervention with subjects? [ ] YES [ ] NO

2. Will investigators collect information that does not currently exist? (i.e., biospecimens that are not currently on the shelf or information from records that does not already exist as of the date of submission of this protocol)? [ ] YES [ ] NO

3. Will investigators collect subject identifiers or have access to a code key linking subjects’ identities to the data or biospecimens? [ ] YES [ ] NO

Note: If you answer YES to any of the above three questions, your protocol does not qualify as Exempt research under Category 4. If another Exempt category does not apply complete the Protocol Narrative for Expedited/Full Committee Research.

B. Number of Biospecimens/Charts/Records/Datasets

Specify the maximum number of records or biospecimens that will be reviewed/analyzed to compile the data necessary to address the research question or the maximum number of individuals that will comprise the dataset.

<Type here>

IMPORTANT TIME SAVER: Complete Part C ONLY if you are requesting permission to study biospecimens.

C. Description of Biospecimens

1. Specify the type(s) of human biospecimens that will be studied:
2. Specify the **source of the biospecimens and** whether the biospecimens were originally **collected solely for research purposes**.

3. If the biospecimens were originally collected for research purposes, please **submit a copy of the IRB Approval Notice and Consent Form for the original collection** of these specimens with the e-IRB Application.

4. Specify how the **biospecimens are identified** when they are made available to the study team. Please indicate by marking the appropriate bracket(s) below.

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<td>[ ] Indirect Identifier</td>
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<td>[ ] Direct Identifier**</td>
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If **ii is checked above**, specify whether the study team will be given access to the key code.

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<tr>
<td>[ ] Yes, the study team will have access to the code key linking the code and subject identities**</td>
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<tr>
<td>[ ] No, the study team will not have access to the code key linking the code and subject identities</td>
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**Note: If direct identifiers will be used or the study team will have access to the code key, the research does not qualify for **Exempt Registration under Category 4**. If another Exempt category does not apply complete the **Protocol Narrative for Expedited/Full Committee Research**.**

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**IMPORTANT TIME SAVER:** Complete Part D ONLY if you are requesting permission to study existing data, charts, or records.

D. Description of Charts/Records/Datasets
1. Specify the **types/sources of records/data** that will be reviewed by selecting the appropriate box below (e.g., census, medical).
2. Please be sure to submit a copy of the **Data Extraction Sheet** that will be used to collect the data for this study (i.e. the document used to record the information)) with the e-IRB Application.

   **Note:** If direct identifiers will be collected on the data abstraction sheet (e.g., medical record number, name), or the study team will have access to the code key linking the code to the subjects’ identities, the research does not qualify for Exempt Registration. STOP completing this form and complete the Protocol Narrative for Expedited or Full Committee Review.

   - [ ] UCI Medical Records
   - [ ] Individual level data from an established data bank or repository (specify): <Type here>
   - [ ] Publicly available information (i.e. DMV, US Census)
   - [ ] NCI SEER (Surveillance Epidemiology and End Results)
   - [ ] Data Sets not including any of the **18 Protected Health Identifiers**
   - [ ] Other (specify): <Type here>

3. Provide a description of how the appropriate **records/data** for study will be provided to the study team. (e.g. the Investigator will ask the Medical Records Department to provide specific charts and/or de-identified data; the Investigator will review his/her own charts and abstract data directly from those charts; the Investigator will be provided an already existing, de-identified data set, etc.)

4. Specify whether the information is **publicly available**.
5. Explain whether the data was originally collected **solely for research purposes**.
6. If the records/data were originally collected for research purposes, please submit a copy of the **IRB Approval Notice and Consent Form for the original collection** of this information with the e-IRB Application.

7. Specify how the **data is identified** when it is **recorded** by the study team. Please indicate by marking the appropriate bracket(s) below.

   - i) [ ] No Identifier  
     (i.e., neither the researcher nor the source providing the data can identify a subject based upon information provided with the data)
   - ii) [ ] Indirect Identifier  
     (i.e., an assigned code will be kept which could be used by the investigator or the source providing data to identify a subject, such as a tracking code used by the source.)
iii) [ ] Direct Identifier** (i.e., subject name, address, social security number, medical record number, etc. will be attached to data)

If ii is checked above, specify whether the study team will be given access to the code.

[ ] Yes, the study team will have access to the link between the tracking code and subject identities.**

[ ] No, the study team will not have access to the link between the code and subject identities.

**Note: Unless the information is publicly available, if direct identifiers will be used, or the study team will have access to the code key linking the code to the subjects’ identities, the research does not qualify for Exempt Registration. STOP completing this form and instead complete the Protocol Narrative for Expedited or Full Committee Review.

SECTION 11: RESEARCH METHODOLOGY/STUDY PROCEDURES

A. Study Design and Procedures

1. Provide a detailed chronological description of all study procedures.
2. Describe how the subject’s privacy will be protected during the research procedures (i.e., during data extraction procedures).

<Type here>