Title: STARTprep: Multi-institutional Evaluation of an Online Curriculum for Anesthesia Board Preparation

Approval Period: 06/10/2013 - 05/31/2014

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Other Personnel

Participant Population(s) Checklist

- Children (under 18) N
- Pregnant Women and Fetuses
- Neonates (0 - 28 days)
- Abortuses
- Impaired Decision Making Capacity
- Cancer Subjects
- Laboratory Personnel
- Healthy Volunteers
- Students
- Employees
- Prisoners
- Other (i.e., any population that is not specified above)

**Study Location(s) Checklist**

- Stanford University
- Clinical & Translational Research Unit (CTRU)
- Stanford Hospital and Clinics
- Lucile Packard Children's Hospital (LPCH)
- VAPAHCS (Specify PI at VA)
- Other (Click ADD to specify details)

**General Checklist**

**Multi-site**

- Is this a multi-site study? A multi-site study is generally a study that involves one or more medical or research institutions in which one site takes a lead role (e.g., multi-site clinical trial)
- Is Stanford the coordinating institution or are you the lead investigator for this multi-site study?
Protocol # 27444 (New)
PD: Dr Lawrence Fu-nien Chu
Review Type: Expedited
Medical

Title: STARTprep: Multi-institutional Evaluation of an Online Curriculum for Anesthesia Board Preparation
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Collaborating Institution(s)

• Are there any collaborating institution(s)? A collaborating institution is generally an institution that collaborates equally on a research endeavor with one or more institutions.

Cancer Institute

• Cancer-Related Studies (studies with cancer endpoints), Cancer Subjects (e.g., clinical trials, behavior/prevention) or Cancer Specimens (e.g., blood, tissue, cells, body fluids with a scientific hypothesis stated in the protocol).

Drug /Device

• Investigational drugs, biologics, reagents, or chemicals?
• Commercially available drugs, reagents, or other chemicals administered to subjects (even if they are not being studied)?
• Investigational Device / Commercial Device used off-label?
• IDE Exempt Device (Commercial Device used according to label)

• Click "yes" to confirm that you have accessed the website and read the clinicaltrials.gov reporting requirements provided.

• This study will be registered on clinicaltrials.gov?

• Protocol involves studying potentially addicting drugs?
Tissues and Specimens

• Human blood, cells, tissues, or body fluids (tissues)? N
• Tissues to be stored for future research projects? N
• Tissues to be sent out of this institution as part of a research agreement? For guidelines, please see http://stanford.edu/group/ICO/researcher/reMTA.html

Biosafety (APB)

• Are you submitting a Human Gene Transfer investigation using biological agent or recombinant DNA vector? If yes, please complete and attach the Gene Transfer Protocol Application Supplemental Questions to section 16 of the eProtocol application. N
• Are you submitting a Human study using samples from subjects that contain biohazardous/infectious agents? If yes, refer to the https://ehsappprd1.stanford.edu/eprobio/ Administrative Panel on BioSafety website prior to performing studies. N

Human Embryos or Stem Cells

• Human Embryos or gametes? N
• Human Stem Cells (including hESC, iPSC, cancer stem cells, progenitor cells). N

Veterans Affairs (VA)

• The research recruits participants at the Veterans Affairs Palo Alto Health Care System (VAPAHCS). N
• The research involves the use of VAPAHCS non-public information to identify or contact human research participants or prospective subjects or to use such data for research purposes. N
• The research is sponsored (i.e., funded) by VAPAHCS. N
• The research is conducted by or under the direction of any employee or agent of VAPAHCS (full-time, part-time, intermittent, consultant, without compensation (WOC), on-station fee-basis, on-station contract, or on-station sharing agreement basis) in connection with her/his VAPAHCS responsibilities. N
• The research is conducted using any property or facility of VAPAHCS. N
Equipment

- Use of Patient related equipment? If Yes, equipment must meet the standards established by Hospital Instrumentation and Electrical Safety Committee (650-725-5000)
- Medical equipment used for human patients/subjects also used on animals?
- Radioisotopes/radiation-producing machines, even if standard of care?

Payment

- Subjects will be paid for participation? See payment considerations.

Funding

- Training Grant?
- Program Project Grant?
- Federally Sponsored Project?
- Industry Sponsored Clinical Trial?

Funding

- Grants/Contracts
- Fellowships
- Gift Funding
- Dept. Funding

Department Name: Anesthesia
Account Number: 1027995-150-EAFGT

Other Funding

Expedited Form

A protocol must be no more than minimal risk (i.e., "not greater than those ordinarily encountered in daily life") AND must only involve human subjects in one or more of the following paragraphs.
Select one or more of the following paragraphs:

1. **N** Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   b) Research on medical devices for which
      i) an investigational device exemption application (21 CFR Part 812) is not required; or
      ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. **N** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. **N** Prospective collection of biological specimens for research purposes by non invasive means.

4. **N** Collection of data through non invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
   Examples:
   a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
   b) weighing or testing sensory acuity;
   c) magnetic resonance imaging;
   d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
   e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. **N** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. **N** Collection of data from voice, video, digital, or image recordings made for research purposes.

7. **Y** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey,
interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Resources:

a) Qualified staff.

Please state and justify the number and qualifications of your study staff.

The study staff is led by Dr. Larry Chu and the Anesthesia Informatics and Media (AIM) lab at Stanford who have extensive experience in conducting and publishing educational informatics research, along the lines of the work proposed in this protocol.

b) Training.

Describe the training you will provide to ensure that all persons assisting with the research are informed about the protocol and their research-related duties and functions.

All personnel assisting with this research will be informed about the protocol by the PD and they will receive training by the PD in the research-related duties and functions of conducting this online course.

c) Facilities.

Please describe and justify.

The Stanford AIM lab is located on the fourth floor of the Grant Building. It has high-powered computing facilities, learning management software and publishing capabilities necessary to support the development and conduct of this educational research project.

d) Sufficient time.

Explain whether you will have sufficient time to conduct and complete the research. Include how much time is required.

The PD has a KO2 grant from the NIH that provides 80% non-clinical time to conduct scientific research.

e) Access to target population.

Explain and justify whether you will have access to a population that will allow recruitment of the required number of participants.

The study will have access to anesthesia residents from 12 institutions in the United States by prior agreement with these institutions, including anesthesia residents at Stanford University.

f) Access to resources if needed as a consequence of the research.

State whether you have medical or psychological resources available that participants might require as a consequence of the research when applicable. Please describe these resources.

We do not anticipate medical or psychological resources being needed as a consequence of participating in
this online educational course designed to help anesthesia residents prepare for the written anesthesia board examination.

g) Lead Investigator or Coordinating Institution in Multi-site Study.

Please explain (i) your role in coordinating the studies, (ii) procedures for routine communication with other sites, (iii) documentation of routine communications with other sites, (iv) planned management of communication of adverse outcomes, unexpected problems involving risk to participants or others, protocol modifications or interim findings.

I) The Stanford PD will prepare research protocols, administer the online course, collect student learning analytics data from the learning management system platform, and coordinate development of course materials among all 12 sites. II) procedures for routine communication with other sites will involve primarily email communications. III) documentation of routine communications with other sites will involve summary communications by email. IV) Planned management of communication of adverse outcomes, unexpected problems involving risk to participants or others, protocol modifications or interim findings will be conducted by group email communications to all sites. Where synchronous communication is required, the PD will arrange for group conference calls.

1. Purpose

a) In layperson's language state the purpose of the study in 3-5 sentences.

The purpose of this study is to determine if completion of an online course designed to prepare anesthesia residents for competency in the basic written board examination results in successful completion of this high stakes educational milestone.

b) State what the Investigator(s) hope to learn from the study. Include an assessment of the importance of this new knowledge.

We hope to gain a better understanding of how online learning can help post-graduate medical trainees learn medicine and prepare for a high stakes examination. We will also look at how various techniques in online education, such as mastery learning and personalized feedback, can enhance student performance on the examination.

The primary assessment outcome measure will be the score the student achieves on the ABA basic written exam. These scores will be reported by each site.

We will correlate overall scores and/or subject area subscores to student performance in the online course. This will help us understand how the online course may predict performance on the high stakes examination.

We will also conduct qualitative assessments of the online course by conducting course evaluations at regular intervals before the course, during the course, upon completion of the course, and after students take the ABA written examination and receive their scores.

c) Explain why human subjects must be used for this project. (i.e. purpose of study is to test efficacy of investigational device in individuals with specific condition; purpose of study is to examine specific behavioral traits in humans in classroom or other environment)

The purpose of this study is to examine the efficacy of an online program to prepare anesthesia trainees for competency in the ABA written examination. Anesthesia trainees are human subjects, therefore human
2. Study Procedures

a) Describe all the procedures, from screening through closeout, which the human subject must undergo in the research project, including study visits, drug treatments, randomization and the procedures that are part of standard of care.

1) Each educational site will provide the coordinating center (Stanford) with the name and email address of the anesthesia residents they wish to enroll in the study.
2) Stanford will send these students an email introducing them to the course and providing them with log-in credentials to access the course website.
3) Students will log into the course on a daily basis for 12 months.
4) Upon each daily login, students will take a short quiz on the topic to be taught that day and then read 6-8 paragraphs of text-based information. Upon completing the reading, they will complete a post-learning assessment of their knowledge.
5) Each month, students will complete a qualitative assessment of the course, giving the PD information such as how to improve the educational value of the course.
6) At the end of the 12-month online course, students will complete a test to measure their overall knowledge gained during the preceding year.
7) At the end of the 12-month online course, students will complete a course evaluation.
8) After taking the ABA written examination, students will complete a course evaluation.
9) Each educational site will provide the PD of the coordinating center (Stanford) with the results of the ABA written examination for each student that was enrolled in the STARTprep course.

b) Explain how the above research procedures are the least risky that can be performed consistent with sound research design.

The research procedures are the least risky that can be performed consistent with sound research design because they use discrete online education techniques and course evaluations to implement a learning intervention that may benefit anesthesia residents in their preparation for competency to take the ABA written examination. It does not use more invasive educational techniques such as in-person simulation, but rather uses online training techniques that can be completed at the learner's own convenience.

c) State if deception will be used. If so, provide the rationale and describe debriefing procedures. Since you will not be fully informing the participant in your consent process and form, complete an alteration of consent (in section 13). Submit a debriefing script (in section 16).

No deception will be used.

d) State if audio or video recording will occur. Describe what will become of the recording after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the recordings.

No audio or video recording will occur.

e) Describe alternative procedures or courses of treatment, if any, that might be advantageous to the participant. Describe potential risks and benefits associated with these. Any standard treatment that is being withheld must be disclosed in the consent process and form. (i.e. standard-of-care drug, different interventional procedure, no procedure or treatment, palliative care, other research studies).

There are no alternative procedures or courses of treatment. No standard treatment is being withheld.

f) Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?
No. At the conclusion of the study, the students must take the ABA written examination and the course will be concluded.

g) **Study Endpoint.** What are the guidelines or end points by which you can evaluate the different treatments (i.e. study drug, device, procedure) during the study? If one proves to be clearly more effective than another (or others) during the course of a study, will the study be terminated before the projected total participant population has been enrolled? When will the study end if no important differences are detected?

The study endpoint will be the conclusion of the 12-month course and obtaining the learner's ABA written examination result.

3. **Background**

   a) **Describe past experimental and/or clinical findings leading to the formulation of the study.**

   Seminal work by Benjamin Bloom (The 2 Sigma Problem: The Search for Methods of Group Instruction as Effective as One-to-One Tutoring, Educational Researcher, Vol. 13, No. 6 (Jun-Jul, 1984), pp. 4-16) has shown that personalized learning can improve student performance. These studies suggest that there may be a learning benefit to online educational programs that aim to personalize the learning experience and scale that ability to large groups of learners. The STARTprep program is such an online education program, that aims to provide personalized learning to large groups of students using online learning. Work by Bloom and colleagues suggests that this online approach may improve learning, compared to traditional classroom teaching.

   Previous studies deploying online spaced learning, similar in some respects to techniques the STARTprep program will employ, demonstrate improvements in learning that persist for up to two years after course completion (Learning benefits of on-line spaced education persist for 2 years. Kerfoot BP. J Urol. 2009 Jun;181(6):2671-3.)

   b) **Describe any animal experimentation and findings leading to the formulation of the study.**

   There are no animal experimental findings relevant to this work.

4. **Radioisotopes or Radiation Machines**

    a) **List all standard of care procedures using ionizing radiation (radiation dose received by a subject that is considered part of their normal medical care). List all research procedures using ionizing radiation (procedures performed due to participation in this study that is not considered part of their normal medical care). List each potential procedure in the sequence that it would normally occur during the entire study.**

<table>
<thead>
<tr>
<th>Identify Week/Month of study</th>
<th>Name of Exam</th>
<th>Identify if SOC or Research</th>
</tr>
</thead>
</table>

    b) **For research radioisotope projects, provide the following radiation-related information:**

   Identify the radionuclide (s) and chemical form (s).

   Provide the number of times the radioisotope and activity that will be administered (mCi) and the route of administration.
If not FDA approved provide dosimetry information and reference the source documents (package insert, MIRD calculation, peer reviewed literature).

c) For research radiation machine projects, provide the following diagnostic procedures:
   For well-established radiographic procedures describe the exam.
   Identify the number of times each will be performed on a single research subject.
   For each radiographic procedure, provide the setup and technique sufficient to permit research subject dose modeling. The chief technologist can usually provide this information.
   For radiographic procedures not well-established, provide FDA status of the machine, and information sufficient to permit research subject dose modeling.

d) For research radiation machine projects, provide the following therapeutic procedures:
   For a well-established therapeutic procedure, identify the area treated, dose per fraction and number of fractions. State whether the therapeutic procedure is being performed as a normal part of clinical management for the research participant's medical condition or whether it is being performed because the research participant is participating in this project.
   For a therapeutic procedure that is not well-established, provide FDA status of the machine, basis for dosimetry, area treated, dose per fraction and number of fractions.

5. Devices

a) Please list in the table below all Investigational Devices (and Commercial Devices used off-label) to be used on participants

b) Please list in the table below all Commercial devices to be used on participants

6. Drugs, Reagents, or Chemicals

a) Please list in the table below all investigational drugs, reagents or chemicals to be administered to participants.

b) Please list in the table below all commercial drugs, reagents or chemicals to be administered to participants.

7. Medical Equipment for Human Subjects and Laboratory Animals

If medical equipment used for human patients/participants is also used on animals, describe such equipment and disinfection procedures.
No medical equipment will be used.
8. Participant Population

a) State the following: (i) the number of participants expected to be enrolled at Stanford-affiliated site(s); (ii) the total number of participants expected to enroll at all sites; (iii) the type of participants (i.e., students, patients with certain cancer, patients with certain cardiac condition) and the reasons for using such participants.

I) 26 residents will be enrolled at the Stanford sites.
II) The total number of participants expected to enroll at all sites is 192 residents.
III) The type of participants are anesthesia residents.

b) State the age range, gender, and ethnic background of the participant population being recruited.

The age range of anesthesia CA-1 residents varies between 27-30 years old, and we do not have specific gender or ethnic background targets for recruitment in this study.

c) State the number and rationale for involvement of potentially vulnerable subjects in the study (including children, pregnant women, economically and educationally disadvantaged, decisionally impaired, homeless people, employees and students). Specify the measures being taken to minimize the risks and chance of harm to the potentially vulnerable subjects and the additional safeguards that have been included in the protocol to protect their rights and welfare.

We plan to enroll students in this study because this is an online educational study designed to assess efficacy in preparing students for competency to take the ABA written examination. Specific measures being taken to minimize the risks and chance of harm to the potentially vulnerable subjects include protection of student privacy (data will only be used for research purposes and will not be published or shared with others outside of the participating research institutions).

d) If women, minorities, or children are not included, a clear compelling rationale must be provided (e.g., disease does not occur in children, drug or device would interfere with normal growth and development, etc.).

Children are not included because they cannot be anesthesia residents, who are the targeted participant population.

e) State the number, if any, of participants who are laboratory personnel, employees, and/or students. They should render the same written informed consent. If payment is allowed, they should also receive it. Please see Stanford University policy at http://www.stanford.edu/dept/DoR/rph/7-5.html).

All participants in this study, expected to be 192, will be students (anesthesia residents).

f) State the number, if any, of participants who are healthy volunteers. Provide rationale for the inclusion of healthy volunteers in this study. Specify any risks to which participants may possibly be exposed. Specify the measures being taken to minimize the risks and the chance of harm to the volunteers and the additional safeguards that have been included in the protocol to protect their rights and welfare.

We will not be assessing the health of the student participants in this educational study.

g) Describe how potential participants will be identified for recruitment (e.g., chart review, referral from individual’s treating physician, responses to an ad). Describe how participants will be recruited and how they will initially learn about the research (e.g., clinics, advertising). If this is a clinical trial, indicate the recruitment option selected in registering the trial on the Stanford Clinical Trials web site—whether recruitment is limited to “invitation only” (e.g. your own patients), or whether recruitment will be open to the general public. Attach recruitment materials in Section #16
You may not contact potential participants prior to IRB approval. See guidance

Potential participants will be identified by each educational site and their names and email addresses will be
sent to the coordinating site’s PD (Stanford).

h) Inclusion and Exclusion Criteria.
Identify inclusion criteria.
Anesthesia resident who has completed clinical base year training.

Identify exclusion criteria.
None.

i) Describe your screening procedures, including how qualifying laboratory values will be obtained. If
you are collecting personal health information prior to enrollment (e.g., telephone screening), please
request a limited waiver of authorization (in section 15).

No screening procedures, other than identifying that the student is an anesthesia resident who has completed
clinical base year training will be performed.

j) Describe how you will be cognizant of other protocols in which participants might be enrolled. Please
explain if participants will be enrolled in more than one study.

Participants will be asked if they are concurrently enrolled in any other research studies. Concurrent
enrollment in other studies may be allowed, as long as such participation does not conflict with the conduct
of this study.

k) Payment. Explain the amount and schedule of payment, if any, that will be paid for participation in the
study. Substantiate that proposed payments are reasonable and commensurate with the expected
contributions of participants and that they do not constitute undue pressure on participants to
volunteer for the research study. Include provisions for prorating payment. See payment
considerations

No payment will be made to participants.

l) Costs. Please explain any costs that will be charged to the participant.
No costs will be charged to the participant.

m) Estimate the probable duration of the entire study. Also estimate the total time per participant for: (i)
screening of participant; (ii) active participation in study; (iii) analysis of participant data.

The entire study will likely last several years. We plan to conduct a multi-year study, but will perform
annual analyses. We plan to study how performance in the STARTprep course influence performance
during the entire 3-year anesthesia curriculum, including performance on ITE, OSCEs and written and oral
board exams.

The time for screening of a participant will take a few minutes, active participation in the study for each
participant will last 12 months, and analysis of participant data will take six months.

9. Risks

a) For the following categories include a scientific estimate of the frequency, severity, and reversibility of potential
risks. Wherever possible, include statistical incidence of complications and the mortality rate of proposed
Where there has been insufficient time to accumulate significant data on risk, a statement to this effect should be included. (In describing these risks in the consent form to the participant it is helpful to use comparisons which are meaningful to persons unfamiliar with medical terminology.)

**Investigational devices.**

No investigational devices will be used.

**Investigational drugs. Information about risks can often be found in the Investigator’s brochure.**

No investigational drugs will be used.

**Commercially available drugs, reagents or chemicals. Information about risks can often be found in the package insert.**

No commercially available drugs will be used.

**Procedures to be performed. Include all investigational, non-investigational and non-invasive procedures (e.g., surgery, blood draws, treadmill tests).**

No investigational, non-investigational or non-invasive procedures will be used.

**Radioisotopes/radiation-producing machines (e.g., X-rays, CT scans, fluoroscopy) and associated risks.**

No radioisotopes/radiation-producing machines will be used.

**Physical well-being.**

We do not anticipate any impact on physical well-being due to participation in this online learning program. To ensure that participant data is not identifiable, if the PGY-1 or CA-1 classes’ each consist of less than five participants, the pooled data will not be shared with the home institution.

**Psychological well-being.**

We do not anticipate any impact on psychological well-being due to participation in this online learning program. To ensure that participant data is not identifiable, if the PGY-1 or CA-1 classes’ each consist of less than five participants, the pooled data will not be shared with the home institution.

**Economic well-being.**

We do not anticipate any impact on economic well-being due to participation in this online learning program. To ensure that participant data is not identifiable, if the PGY-1 or CA-1 classes’ each consist of less than five participants, the pooled data will not be shared with the home institution.

**Social well-being.**

We do not anticipate any impact on social well-being due to participation in this online learning program. To ensure that participant data is not identifiable, if the PGY-1 or CA-1 classes’ each consist of less than five participants, the pooled data will not be shared with the home institution.

**Overall evaluation of Risk.**

Low - innocuous procedures such as phlebotomy, urine or stool collection, no therapeutic agent, or safe therapeutic agent such as the use of an FDA approved drug or device.

b) **In case of overseas research, describe qualifications/preparations that enable you to both estimate and minimize risks to participants.**

No overseas research will be conducted.

c) **Describe the planned procedures for protecting against and minimizing all potential risks. Include the means for monitoring to detect hazards to the participant (and/or to a potential fetus if applicable). Include steps to minimize risks to the confidentiality of identifiable information.**

Steps to minimize risk includes insuring the confidentiality of identifiable information by storing such information securely on our Stanford learning management system servers, de-identifying data when it is
shared with others outside of the Stanford AIM lab, and protecting the individual identity of learners as it relates to their individual learning outcomes. To ensure that participant data is not identifiable, if the PGY-1 or CA-1 classes each consist of less than five participants, the pooled data will not be shared with the home institution.

d) Explain the point at which the experiment will terminate. If appropriate, include the standards for the termination of the participation of the individual participant. Also discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the participants.

Termination of the experiment will take place when the student completes the 12-month online course. We do not anticipate any medical or professional intervention will be required at the end of this online course. If such intervention is required, participants will be referred to such appropriate resources.

10. Benefits

a) Describe the potential benefit(s) to be gained by the participants or by the acquisition of important knowledge which may benefit future participants, etc.

The participants may benefit from their participation in this online course by gaining competency in the ABA written basic examination. Knowledge gained through this research study may allow us to provide high quality online learning programs broadly to all anesthesia residents to assist their gaining competency in the ABA written basic examination.

11. Privacy and Confidentiality

Privacy Protections

a) Describe how the conditions under which interactions will occur are adequate to protect the privacy interests of participants (e.g., privacy of physical setting for interviews or data collection, protections for follow-up interactions such as telephone, email and mail communications).

This is an online course designed to prepare participants for competency in the ABA written examination. Since we do not plan to collect health information from participants, we are not under the jurisdiction of HIPAA.

Confidentiality Protections

b) Specify the PHI (protected health information) or other individually identifiable data or specimens you will obtain, use or disclose to others.

No PHI will be collected.

c) You are required to comply with University Policy that states that ALL electronic devices: computers (laptops and desktops; OFFICE or HOME); smart phones; tablets; external hard disks, USB drives, etc. that may hold identifiable participant data will be password protected, backed up, and encrypted. See http://med.stanford.edu/datasecurity/ for more information on the Data Security Policy and links to encrypt your devices.

Provide any additional information on ALL data security measures you are taking. You must use secure databases such as RedCap https://clinicalinformatics.stanford.edu/services/redcap.html. If you are unsure of the security of the system, check with your Department IT representative. Please see http://med.stanford.edu/irt/security/ for more information on IRT Information Security Services and
http://www.stanford.edu/group/security/securecomputing/mobile_devices.html for more information for securing mobile computing devices. Additionally, any PHI data on paper must be secured in a locked environment.

By checking this box, You affirm the aforementioned. Y

We will not be collecting PHI. We will used encrypted secure computers for all data analysis.

d) Describe how data or specimens will be labeled (e.g. name, medical record number, study number, linked coding system) or de-identified. If you are de-identifying data or specimens, who will be responsible for the de-identification? If x-rays or other digital images are used, explain how and by whom the images will be de-identified.

Data will be collected through an online learning management system. Participants will be identified by a username. We will not be collecting health information. This username will be connected to a real identity by the coordinating site's PD (Stanford). This key will be stored on an encrypted computer system.

e) Indicate who will have access to the data or specimens (e.g., research team, sponsors, consultants) and describe levels of access control (e.g., restricted access for certain persons or groups, access to linked data or specimens).

The Stanford AIM lab will have access to the data. We may also provide data to educational sites participating in the study.

f) If data or specimens will be coded, describe the method in which they will be coded so that study participants' identities cannot be readily ascertained from the code.

We plan to code data by site name (e.g. Stanford_1) so the students name will not be in the code.

g) If data or specimens will be coded, indicate who will maintain the key to the code and describe how it will be protected against unauthorized access.

The coordinating site's PD will maintain the key and it will be stored on an encrypted computer.

h) If you will be sharing data with others, describe how data will be transferred (e.g., courier, mail) or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, describe how you will secure the data while in transit. See http://www.stanford.edu/group/security/securecomputing/.


We will electronically distribute the file using Stanford's secure file transfer system (http://mss.stanford.edu)

i) How will you educate research staff to ensure they take appropriate measures to protect the privacy of participants and the confidentiality of data or specimens collected (e.g. conscious of oral and written communications, conducting insurance billing, and maintaining paper and electronic data)?

All AIM lab research staff will be trained by the PD in proper data security measures, including the use of encrypted computers. Please note again, we are not collecting any health information, so no PHI will be collected.

12. Potential Conflict of Interest

New PHS regulations require that financial interests must be disclosed by investigators, and those that are identified as financial conflicts of interest must be eliminated or managed prior to final approval of this protocol.
When the Personnel section of this protocol is completed, the faculty investigators will receive an email notifying them of the OPACS requirement. They may either answer "No" to the Financial Interest question from the email, or go to their OPACS dashboard to answer the question.

Investigators who have not received an email from OPACS can still complete their disclosures by going to their OPACS dashboard directly at opacsprd.stanford.edu. They should contact their school's COI Manager with any issues with OPACS.

The table below displays the names of investigators and whether they have entered their financial interest disclosure, & S/B disclosure, if any, in OPACS and the status of review of conflicts of interest.

You will not be able to submit this protocol until the ”Financial Interest” question has been answered in OPACS for all investigators listed in the table below.

Review of this protocol by IRB will occur when all investigators listed below have answered Yes or No to the Financial Interest question in OPACS.

Approval of this protocol will only occur when all investigators who have Financial Interests have submitted their OPACS disclosure and review of the information has been completed by the COI Manager.

Note: If any changes to disclosures are made while this page is open, simply reload the page to see current information.

<table>
<thead>
<tr>
<th>Investigators</th>
<th>Role</th>
<th>Email</th>
<th>Has Financial Interest?</th>
<th>Date Financial Interest Answered</th>
<th>Date OPACS Disclosure Submitted</th>
<th>Date OPACS Review Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Lawrence Fu-nien Chu</td>
<td>PD</td>
<td><a href="mailto:LCHU@STANFORD.EDU">LCHU@STANFORD.EDU</a></td>
<td>N</td>
<td>04/12/2013</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

13. Consent Background

13.1 Waiver of Documentation

Sponsor's Consent Version Number: (if any):

a) Describe the informed consent process. Include the following.
   i) Who is obtaining consent? (The person obtaining consent must be knowledgeable about the study.)
   ii) When and where will consent be obtained?
   iii) How much time will be devoted to consent discussion?
   iv) Will these periods provide sufficient opportunity for the participant to consider whether or not to participate and sign the written consent?
   v) What steps are you taking to minimize the possibility of coercion and undue influence?
   vi) If consent relates to children and if you have a reason for only one parent signing, provide that rationale for IRB consideration.
I) The coordinating site will obtain the consent on the program website using text prepared by the coordinating site PD (Stanford). II) Consent will be obtained on the course website. III) This is an online consent, so no discussion will occur. IV) The participant will read the information in this document and can take as much time as they like to consider whether or not to participate in the study. V) Participation is optional and no payment is being made, so coercion and undue influence is minimized. VI) No children will be recruited.

b) What is the Procedure to assess understanding of the information contained in the consent? How will the information be provided to participants if they do not understand English or if they have a hearing impairment? See /hrpp/Chapter12.html#ch12_2 HRPP Chapter12.2 for guidance.

All participants will speak English as they are anesthesia trainees in US departments of anesthesiology.

c) What steps are you taking to determine that potential participants are competent to participate in the decision-making process? If your study may enroll adults who are unable to consent, describe (i) how you will assess the capacity to consent, (ii) what provisions will be taken if the participant regains the capacity to consent, (iii) who will be used as a legally authorized representative, and (iv) what provisions will be made for the assent of the participant.

All participants are medical doctors, and therefore deemed competent to participate in the decision-making process. We will not enroll adults who are unable to consent.

Select one of the following regulatory criteria for a waiver of documentation (signature) and provide a protocol-specific justification:

1) 45 CFR 46.117(c)(1). For research that is not subject to FDA regulation, the only record linking the participants and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality; each participant will be asked whether he/she wants documentation linking the participant with the research, and the participant’s wishes govern.

2) 45 CFR 46.117(c)(2). For research that is not subject to FDA regulation, presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

2) 21 CFR 56.109(c)(1). For research that is subject to FDA regulation, presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

Rationale for above selection:
This is an educational research study that has minimal risk of harm and involves no procedures for which written consent is normally required outside of the research context.

14. Assent Background (less than 18 years of age)

15. HIPAA Background

16. Attachments

<table>
<thead>
<tr>
<th>Attachment Name</th>
<th>Attached Date</th>
<th>Attached By</th>
<th>Submitted Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>STARTprep Surveys for IRB</td>
<td>05/06/2013</td>
<td>merlends</td>
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Obligations

The Protocol Director agrees to:

- Adhere to principles of research designed to yield valid results
  http://humansubjects.stanford.edu/research/documents/eval_study_designGUI03017.pdf
- Conduct the study according to the protocol approved by the IRB
- Be appropriately qualified to conduct the research and be trained in Human Research protection, ethical principles, regulations, policies and procedures
- Ensure all research personnel are adequately trained and supervised
- Ensure that the rights and welfare of participants are protected including privacy and confidentiality of data
- Disclose to the appropriate departments any potential conflict of interest
- Report promptly any new information, modification, or unanticipated problems that raise risks to participants or others
- Apply relevant professional standards.

VA Protocol Directors also certify that:

- All unanticipated internal or local SAEs, whether related or unrelated to the research, will be/have been reported to the IRB
- All subjects entered onto the master list of subjects for the study will sign/have signed an informed consent form prior to undergoing any study interactions or interventions, unless granted a waiver by the IRB.

Any change in the research protocol must be submitted to the IRB for review prior to the implementation of such change. Any complications in participants or evidence of increase in the original estimate of risk should be reported at once to the IRB before continuing with the project. Inasmuch as the Institutional Review Board (IRB) includes faculty, staff, legal counsel, public members, and students, protocols should be written in language that can be understood by all Panel members. The investigators must inform the participants of any significant new knowledge obtained during the course of the research.

IRB approval of any project is for a maximum period of one year. For continuing projects and activities, it is the responsibility of the investigator(s) to resubmit the project to the IRB for review and re-approval prior to the end of the approval period. A Notice to Renew Protocol is sent to the Protocol Director 7 weeks prior to the expiration date of the protocol.

Department Chair must approve faculty and staff research that is not part of a sponsored project. VA applicants must have Division Chief or Ward Supervisor approval. E-mail the Department Chair approval to
IRBCoordinator@lists.stanford.edu.

All data including signed consent form documents must be retained for a minimum of three years past the completion of the research. Additional requirements may be imposed by your funding agency, your department, or other entities. (Policy on Retention of and Access to Research Data, Research Policy Handbook, http://www.stanford.edu/dept/DoR/rph/2-10.html)

PLEASE NOTE: List all items (verbatim) that you want to be reflected in your approval letter (e.g., Amendment, Investigator's Brochure, consent form(s), advertisement, etc.) in the box below. Include number and date when appropriate.

Y The Protocol Director has read and agrees to abide by the above obligations.