**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia Residency Training?

**Approval Period:** 06/03/2013 - 05/31/2014

## Protocol Director

| Name | | Degree (program/year if student) | | Title |
|---|---|---|---|---|
| Dr Lawrence Fu-nien Chu | | | | Asst Prof-Med Ctr Li |
| **Dept** | **Mail Code** | **Phone** | **Fax** | **E-mail** |
| Anesthesia | 5640 | 650-723-4671 | | LCHU@STANFORD.EDU |
| **CITI Training current** | | | | Y |

## Admin Contact

| Name | | Degree (program/year if student) | | Title |
|---|---|---|---|---|
| Matthew Erlendson | | | | Social Science Research Asst |
| **Dept** | **Mail Code** | **Phone** | **Fax** | **E-mail** |
| Anesthesia | 5117 | 650-723-4671 | | matthewerlendson@gmail.com |
| **CITI Training current** | | | | N |

## Co-Protocol Director

| Name | | Degree (program/year if student) | | Title |
|---|---|---|---|---|
| Dr Thomas Kyle Harrison | | | | Clinical Assistant P |
| **Dept** | **Mail Code** | **Phone** | **Fax** | **E-mail** |
| Anesthesia Group D | | (650) 723-6411 | | kharriso@stanford.edu |
| **CITI Training current** | | | | Y |

## Other Contact

| Name | | Degree (program/year if student) | | Title |
|---|---|---|---|---|
| **Dept** | **Mail Code** | **Phone** | **Fax** | **E-mail** |
| **CITI Training current** | | | | |

## Faculty Sponsor

| Name | | Degree (program/year if student) | | Title |
|---|---|---|---|---|
| **Dept** | **Mail Code** | **Phone** | **Fax** | **E-mail** |
| **CITI Training current** | | | | |

## Other Personnel

| Name | | Degree (program/year if student) | | Title |
|---|---|---|---|---|
| Mr. Sanford Eugene Roberts | | | | |
| **Dept** | **Mail Code** | **Phone** | **Fax** | **E-mail** |
| Program in Human Biology | 6150 | 650-723-4671 | | robsan24@stanford.edu |

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

| | |
|---|---|
| **CITI Training current** | Y |

| **Participant Population(s) Checklist** | **Yes/No** |
|---|---|
| • Children (under 18) | N |
| • Pregnant Women and Fetuses | N |
| • Neonates (0 - 28 days) | N |
| • Abortuses | N |
| • Impaired Decision Making Capacity | N |
| • Cancer Subjects | N |
| • Laboratory Personnel | N |
| • Healthy Volunteers | Y |
| • Students | Y |
| • Employees | N |
| • Prisoners | N |
| • Other (i.e., any population that is not specified above) | N |

| **Study Location(s) Checklist** | **Yes/No** |
|---|---|
| • Stanford University | Y |
| • 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) | Y |

| Location Name | Contact Name | Contact Phone | Contact Email | Permission? | IRB? |
|---|---|---|---|---|---|
| Yale School of Medicine | | | | Y | Y |
| UC Davis School of Medicine | | | | Y | Y |
| Mount Sinai School of Medicine | | | | Y | Y |
| Harvard Medical School | | | | Y | Y |

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

| | | | | | |
|---|---|---|---|---|---|
| Baylor College of Medicine | | | | Y | Y |
| University of Massachusetts Medical School | | | | Y | Y |
| Jefferson Medical College | | | | Y | Y |
| UC San Diego School of Medicine | | | | Y | Y |
| Tulane University School of Medicine | | | | Y | Y |
| University of Calgary School of Medicine | | | | Y | Y |
| University of Saskatchewan School of Medicine | | | | Y | Y |
| Tufts University School of Medicine | | | | Y | Y |
| George Washington University School of Medicine | | | | Y | Y |
| University of Alabama School of Medicine | | | | Y | Y |
| University of Colorado Denver School of Medicine | | | | Y | Y |
| St. Elizabeth Medicine Center | | | | Y | Y |

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

## General Checklist

**Multi-site** **Yes/No**

- 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) Y
- Is Stanford the coordinating institution or are you the lead investigator for this multi-site study? Y

| Site Name | Contact Name | Contact Phone | Contact Email | Permission? | IRB? |
|---|---|---|---|---|---|
| Yale University School of Medicine | | | | Y | Y |
| UC Davis School of Medicine | | | | Y | Y |
| Mount Sinai School of Medicine | | | | Y | Y |
| Harvard Medical School | | | | Y | Y |
| Baylor College of Medicine | | | | Y | Y |
| University of Massachusetts Medical School | | | | Y | Y |
| Jefferson Medical College | | | | Y | Y |
| UC San Diego School of Medicine | | | | Y | Y |
| Tulane University School of Medicine | | | | Y | Y |
| University of Calgary School | | | | Y | Y |

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

| | | | | | |
|---|---|---|---|---|---|
| of Medicine | | | | | |
| University of Saskatchewan School of Medicine | | | | Y | Y |
| Tufts University School of Medicine | | | | Y | Y |
| George Washington University School of Medicine | | | | Y | Y |
| University of Alabama School of Medicine | | | | Y | Y |
| University of Colorado Denver School of Medicine | | | | Y | Y |
| St. Elizabeth Medicine Center | | | | Y | Y |

**Collaborating Institution(s)** **Yes/No**

- 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. N

**Cancer Institute** **Yes/No**

- 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). N

**Drug /Device** **Yes/No**

- Investigational drugs, biologics, reagents, or chemicals? N
- Commercially available drugs, reagents, or other chemicals administered to subjects (even N

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

if they are not being studied)?

- Investigational Device / Commercial Device used off-label? N
- IDE Exempt Device (Commercial Device used according to label) N

- 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? N

**Tissues and Specimens** **Yes/No**

- 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 http://stanford.edu/group/ICO/researcher/reMTA.html N

**Biosafety (APB)** **Yes/No**

- 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 biohazardous/infectious agents? If yes, refer to the http://www.stanford.edu/dept/EHS/prod/researchlab/bio/index.html Administrative Panel on BioSafety website prior to performing studies. N
- Are you submitting a Human study using samples from subjects that contain biohazardous/infectious agents? If yes, refer to the https://ehsapprd1.stanford.edu/eprobio/ Administrative Panel on BioSafety website prior to performing studies. N

**Human Embryos or Stem Cells** **Yes/No**

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

**Veterans Affairs (VA)** **Yes/No**

- The research recruits participants at the Veterans Affairs Palo Alto Health Care System(VAPAHCS). N

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

| | |
|---|---|
| • 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** | **Yes/No** |
|---|---|
| • Use of Patient related equipment? If Yes, equipment must meet the standards established by Hospital Instrumentation and Electrical Safety Committee (650-725-5000) | N |
| • Medical equipment used for human patients/subjects also used on animals? | N |
| • Radioisotopes/radiation-producing machines, even if standard of care? | N |

| **Payment** | **Yes/No** |
|---|---|
| • Subjects will be paid for participation? See payment considerations. | N |

| **Funding** | **Yes/No** |
|---|---|
| • Training Grant? | N |
| • Program Project Grant? | N |
| • Federally Sponsored Project? | N |
| • Industry Sponsored Clinical Trial? | N |

## Funding

### Funding - Grants/Contracts

### Funding - Fellowships

### Gift Funding

### Dept. Funding

**Department Name:** Anesthesia **Account Number:** 1027995-150-eafgt

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

## 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**

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

**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.**

This study requires three staff-members. Dr. Chu, the primary investigator, will oversee the project and in the development of surveys to be administered to incoming PGY-1 anesthesia interns and current first-year Anesthesia residents in Stanford Medical School and partnered multi-site institutions. Matthew Erlendson and/or Sanford Roberts will serve as the project administrator of educational content.

**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.**

No training is necessary. Once the online curriculum is developed, the residents will be able to take the online curriculum independently.

**c) Facilities.**

**Please describe and justify.**

The proposed course would be online. The course participants, current PGY-1 interns and CA-1 residents at the Stanford Medical School and multi-site institutions, would complete the online curriculum on their personal computers or on an anonymous paper form.

**d) Sufficient time.**

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

START is an annual educational program. Data will be analyzed at the conclusion of each year.

**e) Access to target population.**

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

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

The population of interest is current CA-1 and PGY-1 first-year anesthesia residents at Stanford and participating multi-site institutions.

**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.**

N/A

**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.**

Our team will be responsible for educational content dissemination via online learning management systems. Students (at Stanford and at multi-site institutions) will have password and secured access to the "moodle" online learning management system. The educational content will be unlocked and made available to anesthesia residents and/or medical interns in monthly modules. As this is an online educational study we do not believe that there is significant risk to participants. All participants are anesthesia residents at participating institutions and are assumed to be in good physical and mental health.

## 1. Purpose

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

The purpose of this multicenter observational study is to test whether START, a 10-month online educational program, increases anesthesia knowledge and general well being, increases interns' self-assessed preparedness to begin anesthesia training, and to determine if these results are generalizable across institutions.

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

START will assess whether or not the program increases anesthesia knowledge and general well being, increases interns' self-assessed preparedness to begin anesthesia training, and to determine if these results are generalizable across institutions. This study aims to improve future medical education and assess the viability of online learning modules.

**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 the study is to determine whether or not START increases anesthesia knowledge and general well being, increases interns' self-assessed preparedness to begin anesthesia training and to determine if these results are generalizable across institutions. The study requires the individuals to answer the survey questions in order to obtain the required data.

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

## 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.**

The subject must be notified of the existence of the course content and the purpose of the survey must be explained. Students will be contacted via e-mail with contact information provided by participating institution residency coordinators. Participation in START is not mandatory, however, full-participation is encouraged. A recruitment e-mail is sent to each student with instructions on how to set up their online accounts and access to their initial survey. The initial survey will inform students that START is a research study and that by completing this study they agree to participate in research. Each month from September - June students will be given a monthly learning module. Each module includes five components: short video podcasts, longer coursecast video lectures, interactive/collaborative activities, pre- and post-quizzes, and an evaluation/feedback component. At the beginning of each month students will receive an e-mail that reminds them to complete the monthly learning module.

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

These procedures pose no foreseeable risk to the human subjects.

**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 possible for this study.

**f) Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?**

There is no therapy involved in this study.

**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?**

Each cohort of START students will be enrolled in the START study for 10 months (September - June) which will mark the completion of the START study for those participants. However, the START study will continue for the next years incoming students.

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

## 3. Background

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

There are no past experiments or clinical findings

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

N/A

## 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.**

| Identify Week/Month of study | Name of Exam | Identify if SOC or Research |
|---|---|---|

**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 participants'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

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

**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 in this study.

## 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.**

The amount of participants at other sites will vary based on the number of PGY-1 and CA-1 residents reported at each respective site. The participants population will be current, first-year CA-1, and incoming PGY-1 residents in anesthesia at Stanford and multi-site instituions. These participants are used because the study aims to validate an online curriculum and virtual mentorship program for this population.

Participants by site:

Stanford: Approximately 52 participants from the Stanford School of Medicine are expected to be enrolled.

Yale: Approximately 38 participants from the Yale School of Medicine are expected to be enrolled.

UC Davis: Approximately 28 participants from the UC Davis School of Medicine are expected to be enrolled.

Mount Sinai: Approximately 50 participants from the Mount Sinai School of Medicine are expected to be enrolled.

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

Harvard: Approximately 66 participants from the Harvard Medical School are expected to be enrolled.

Baylor: Approximately 28 participants from the Baylor College of Medicine are expected to be enrolled.

University of Massachusetts: Approximately 18 participants from the University of Massachusetts School of Medicine are expected to be enrolled.

Jefferson Medical School: Approximately 32 participants from the Jefferson Medical School are expected to be enrolled.

UC San Diego: Approximately 24 participants from the UC San Diego School of Medicine are expected to be enrolled.

Tulane School of Medicine: Approximately 10 participants from the Tulane School of Medicine are expected to be enrolled.

University of Calgary School of Medicine: Approximately 12 participants from the University of Calgary School of Medicine are expected to be enrolled.

University of Saskatchewan School of Medicine: Approximately 12 participants from the University of Saskatchewan School of Medicine are expected to be enrolled.

Tufts University School of Medicine: Approximately 18 participants from the Tufts University School of Medicine are expected to be enrolled.

George Washington School of Medicine: Approximately 18 participants from the George Washington School of Medicine are expected to be enrolled.

University of Alabama School of Medicine: Approximately 42 participants from the University of Alabama School of Medicine are expected to be enrolled.

UC Denver School of Medicine: Approximately 24 participants from the UC Denver School of Medicine are expected to be enrolled.

St. Elizabeth Medical Center: Approximately 20 participants from the St. Elizabeth Medical Center are expected to be enrolled.

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

We assume that the subjects will range in age from twenty to forty years. The population is mixed gender and mixed ethnic background.

**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 the 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.**

There are no potentially vulnerable subjects involved in this study. CA-1 and PGY-1 anesthesia residents at Stanford and multi-site institutions are assumed to be in good physical and mental health.

**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**

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

**development, etc.).**

N/A

**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).**

N/A

**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.**

All the participants are healthy volunteers. The population of interest, current first-year CA-1 and PGY-1 anesthesia residents (or interns) at Stanford, they are assumed to be in good physical and mental health. The administration of the surveys and online learning modules pose no risk to the participants.

**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 (Attachments). You may not contact potential participants prior to IRB approval. See guidance Advertisements: Appropriate Language for Recruitment Material.**

Participants will be identified and subsequently recruited based on their status as current (or future) first-year CA-1 residents in anesthesia at Stanford and participating multi-site institutions. Patients will be recruited via email.

**h) Inclusion and Exclusion Criteria.**

**Identify inclusion criteria.**

To qualify for this study, participants must be current (or future) first-year CA-1 and PGY-1 residents in anesthesia at Stanford or participating multi-site institutions.

**Identify exclusion criteria.**

Anyone who is not a current (or future) first-year CA-1 or PGY-1 resident in anesthesia at Stanford or participating multi-site institutions is not eligible for this study.

**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).**

N/A

**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.**

N/A

**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**

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

**considerations**

The participants will not be paid.

**l) Costs. Please explain any costs that will be charged to the participant.**

N/A

**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 screening process will require obtaining a list of current (and future) first-year CA-1 and PGY-1 residents in anesthesia at Stanford and participating multi-site institutions. The participants' interaction with the study will require approximately one hour per monthly module. Analysis of the participant data will require approximately one month. The duration of the active participation for students is 10 months. The START study will have new cohort of incoming students at the end of each academic year.

## 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 procedures. 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.**

None.

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

None.

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

None.

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

None.

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

None.

**Physical well-being.**

None.

**Psychological well-being.**

None.

**Economic well-being.**

None.

**Social well-being.**

None.

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

**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.**

N/A

**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.**

The survey is not expected to cause appreciable risk to participants.

**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.**

The experiment will terminate after the survey results have been collected and analyzed for each academic year. START will continue as an annual education research project for further data collection.

## 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.**

This study will help us validate the usefulness of a teaching and mentorship program. The potential benefits of the participants is enhancement of resident learning experiences.

## 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).**

No PHI will be collected in this online educational study.

### 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 in this online educational study.

**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**

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

**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 an locked environment.**

**By checking this box, You affirm the aforementioned.** Y

The survey results will be maintained through a password protected, online database. Only survey administrators will have access to the survey results.

**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.**

N/A

**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).**

Only the research team will have access to the survey results.

**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.**

Each participant will receive a coded number which will be linked to their identity. The key will be stored in a safe in Grant Room S238.

**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 data will be coded for analysis and the key to the code will be stored in a locked safe in Grant building Room S238. Only the PI will have access to the safe.

**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/. http://www.stanford.edu/group/security/securecomputing/. Additionally, if you will be using or sharing PHI see http://hipaa.stanford.edu/policy_security.html http://hipaa.stanford.edu/policy_security.html.**

Data will not be shared with others.

**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)?**

The research staff, all of whom are trained to work with PHI, will be discouraged from discussing survey results with people unassociated with the study. All survey results will be kept confidential.

## 12. Potential Conflict of Interest

New PHS regulations require that financial interests must be disclosed by investigators, and those that are

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

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.

| Investigators | Role | Email | Has Financial Interest? | Date Financial Interest Answered | Date OPACS Disclosure Submitted | Date OPACS Review Completed |
|---|---|---|---|---|---|---|
| Dr Lawrence Fu-nien Chu | PD | LCHU@STANFORD.EDU | N | 05/06/2013 | N/A | N/A |

## 13. Consent Background

### 13.1 Waiver of Documentation Waiver_for_website_use_revision

**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?**

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

**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 note 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 anesthesia.

**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)** | Y | **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

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

| Attachment Name | Attached Date | Attached By | Submitted Date |
|---|---|---|---|
| START Research Protocol | 05/06/2013 | merlends | |
| START Survey Materials | 05/06/2013 | merlends | |
| START_Recruitment_E-mail_Pediatrics_27657(Revision#1)-1 | 06/03/2013 | kmurphy | |
| START_Recruitment_E-mail_CA-1_27657(Revision#1)-4 | 06/03/2013 | kmurphy | |

## Obligations

The Protocol Director agrees to:

- Adhere to principles of http://humansubjects.stanford.edu/research/documents/eval_study_designGUI03017.pdf sound scientific research designed to yield valid results
- 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 http://humansubjects.stanford.edu/research/documents/Events-Info-Report-to-IRB_GUI03P13.pdf 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.

**Title:** Does an Multicenter-Online, One Year Long, Pre-Residency Anesthesia Curriculum and Virtual Mentorship Program Improve CA-1 Self-Assessed Preparedness for Transition to Anesthesia R . . .

**Approval Period:** 06/03/2013 - 05/31/2014

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.