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# **APPROVAL NOTICE**

DATE:	9/4/2015
TO:	MARK EAGAN EDUCATION
FROM:	TODD FRANKE, PhD Chair, NGIRB
RE:	IRB#10-000564-AM-00010 Amendment for IRB#10-000564-AM-00010 Cooperative Institutional Research Program (CIRP) College Senior Survey Version: Version 1.3 7/18/14

The UCLA Institutional Review Board (UCLA IRB) has approved the above-referenced study. UCLA's Federalwide Assurance (FWA) with Department of Health and Human Services is FWA00004642.

### **Submission and Review Information**

Type of Submission	Amendment
Type of Review	Full Board
Approval Date	9/3/2015
Expiration Date of the Study	5/6/2016
Initial IRB Approval Type	Full Board

## **Regulatory Determinations**

-- Waiver of Signed Informed Consent - The UCLA IRB waived the requirement for signed informed consent for the research under 45 CFR 46.117(c)(2). However, subjects should be provided with an information sheet describing the study.

#### Currently approved recruitment and/or consent documents:

Il locument Name	Document
Document Name	Version #

10-000564 - 2016 CSS Email Invitations and	0.01
Reminders.docx.pdf	
10-000564 - Informed Consent (Clean).docx.pdf	0.01
10-000564 - 2016 CSS Invitation and Reminder	0.01
<u>Templates.docx.pdf</u>	0.01

*Important Note:* Approval by the Institutional Review Board does not, in and of itself, constitute approval for the implementation of this research. Other UCLA clearances and approvals or other external agency or collaborating institutional approvals may be required before study activities are initiated. Research undertaken in conjunction with outside entities, such as drug or device companies, are typically contractual in nature and require an agreement between the University and the entity.

#### **General Conditions of Approval**

As indicated in the PI Assurances as part of the IRB requirements for approval, the PI has ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the IRB.

The PI and study team will comply with all UCLA policies and procedures, as well as with all applicable Federal, State, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- Ensuring that the personnel performing the project are qualified, appropriately trained, and will adhere to the provisions of the approved protocol,
- Implementing no changes in the approved protocol or consent process or documents without prior IRB
  approval (except in an emergency, if necessary to safeguard the well-being of human subjects and then
  notifying the IRB as soon as possible afterwards),
- Obtaining the legally effective informed consent from human subjects of their legally responsible representative, and using only the currently approved consent process and stamped consent documents, as appropriate, with human subjects,
- Reporting serious or unexpected adverse events as well as protocol violations or other incidents related to the protocol to the IRB according to the OHRPP reporting requirements.
- Assuring that adequate resources to protect research participants (i.e., personnel, funding, time, equipment and space) are in place before implementing the research project, and that the research will stop if adequate resources become unavailable.
- Arranging for a co-investigator to assume direct responsibility of the study if the PI will be unavailable to direct
  this research personally, for example, when on sabbatical leave or vacation or other absences. Either this
  person is named as co-investigator in this application, or advising IRB via webIRB in advance of such
  arrangements.