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APPROVAL NOTICE

DATE:	7/18/2014
TO:	MARK EAGAN EDUCATION
FROM:	TODD FRANKE, PhD Chair, NGIRB
RE:	IRB#10-000710-AM-00009 Amendment #9 for webIRB Study IRB#10-000710 Designing an Assessment of the First College Year Version: Version 1.4 7/15/14

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 (IRB00000174).

Submission and Review Information

Type of Submission	Amendment
Type of Review	Expedited
Approval Date	7/18/2014
Expiration Date of the Study	7/2/2015

Specific Conditions for Approval

-- **Final Instruments/Measures** - Please submit the final version of your recruitment and consent material for the 2014-2015 "Your First College Year" survey as an amendment as soon as they become available so that they can be reviewed and approved by the UCLA IRB before implementation.

Regulatory Determinations

-- **Waiver of Signed Informed Consent** - The UCLA IRB waived the requirement for signed informed consent for participation in the study under 45 CFR 46.117(c)(2).

Currently approved recruitment and/or consent documents:

Document Name	Document Version #
10-000710_2014 Student Information Sheet (SIS) (Clean).pdf.pdf	0.02
10-000710_2014 Email Invitation and Reminder Templates (Clean).pdf.pdf	0.02
10-000710_2014 YFCY Email Invitation and Reminder Templates.pdf.pdf	0.02
10-000710_2014 Web Reminder (Clean).pdf.pdf	0.02

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.