OFFICE OF RESEARCH SUPPORT

THE UNIVERSITY OF TEXAS AT AUSTIN

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FWA # 00002030

Date: **03/04/11**

PI(s): **Alma Itze Flores** Department & Mail Code: **CURR & INSTRUCT DEPT**

Title: **Decolonizing Minds: The Experiences of Latina Mexican American Studies Majors at a Predominately White Institution**

IRB EXPEDITED APPROVAL: IRB Protocol # **2010-11-0033**

Dear: **Alma Itze Flores**

In accordance with the Federal Regulations the Institutional Review Board (IRB) reviewed the above referenced research study and found it met the requirements for approval under the Expedited category noted below for the following period of time: **03/04/2011 - 03/03/2012**. *Expires 12 a.m. [midnight] of this date.*

Expedited category of approval:

☐ **(1)** 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)** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant 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 children2, 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)** Prospective collection of biological specimens for research purposes by Non-invasive means. Examples:
(a) hair and nail clippings in a non-disfiguring manner;
(b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
(c) permanent teeth if routine patient care indicates a need for extraction;
(d) excreta and external secretions (including sweat);

(e) uncannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
(f) placenta removed at delivery;
(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
(h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the Process is accomplished in accordance with accepted prophylactic techniques;
(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
(j) sputum collected after saline mist nebulization.

☐ **(4)** Collection of data through noninvasive 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)** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category 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)** Collection of data from voice, video, digital, or image recordings made for research purposes.

☒ **(7)** 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).

☒ Use the attached approved informed consent.

☐ You have been granted a Waiver of Documentation of Consent according to 45 CFR 46.117 and/or 21 CFR 56.109(c)(1).

☐ You have been granted a Waiver of Informed Consent according to 45 CFR 46.116(d).

Responsibilities of the Principal Investigator:

1. Report immediately to the IRB any unanticipated problems.

2. Ensure the proposed changes in the approved research during the IRB approval period will not be applied without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject. Changes in approved research implemented without IRB review and approval initiated to eliminate apparent immediate hazards to the subject must be promptly reported to the IRB, and will be reviewed under the unanticipated problems policy to determine whether the change was consistent with ensuring the subjects continued welfare.

3. Report any significant findings that become known in the course of the research that might affect the willingness of subjects to continue to participate.

4. Ensure that only persons formally approved by the IRB enroll subjects.

5. Use only a currently approved consent form (remember that approval periods are for 12 months or less).

6. Protect the confidentiality of all persons and personally identifiable data, and train your staff and collaborators on policies and procedures for ensuring the privacy and confidentiality of subjects and their information.

7. Submit for review and approval by the IRB all modifications to the protocol or consent form(s) prior to the implementation of the change.

8. Submit a Continuing Review Application for continuing review by the IRB. Federal regulations require IRB review of on-going projects no less than once a year (a Continuing Review Application and a reminder letter will be sent to you two months before your expiration date). If a reminder is not received from Office of Research Support (ORS) about your upcoming continuing review, it is still the primary responsibility of the Principal Investigator not to conduct research activities on or after the expiration date. The Continuing Review Application must be submitted, reviewed and approved, before the expiration date.

9. Upon completion of the research study, a Closure Report must be submitted to the ORS.

10. Include the IRB study number on all future correspondence relating to this protocol.

If you have any questions call or contact the ORS (Mail Code A3200) or via e-mail at orsc@uts.cc.utexas.edu.

Sincerely,

Jody L. Jensen, Ph.D.
Professor
Chair, Institutional Review Board