

"Preventing HIV Risk Behaviors among Hispanic Adolescents"

**Attachment 6b: Local IRB Approval
(University of Miami)**

FULL BOARD – APPROVED AS MODIFIED

June 18, 2008

Guillermo Prado, PhD
University of Miami
Center for Family Studies
Medical Campus, Locator Code: D22

HSRO STUDY NUMBER: **20080117**
STUDY TITLE: **Preventing HIV Risk Behaviors among Hispanic Adolescents**
IRB MEETING DATE: **6/12/2008**
STUDY APPROVAL
EXPIRES: **6/11/2009**

On June 12, 2008, the Social and Behavioral Sciences IRB determined that the above referenced study is **approved as modified**. This study has been approved for the inclusion of minors pursuant to 45 CFR 46.405. This review confirms that the grant application is consistent with the goals of the research proposed.

APPROVAL INCLUDES:

New Research Protocol
Grant Award # PS07-003, Minority HIV/AIDS Research Initiative (MARI)
Research Materials (English Versions Only)

- Adolescent Assessment Battery
- Parent Assessment Battery
- Recruitment Flyer

NOTE: Translations of IRB approved study documents, including informed consent documents, into languages other than English must be submitted to HSRO for approval prior to use.

NOTE: Please note that no subjects are to be enrolled until a Certificate of Confidentiality is obtained from the NIH. Once one is obtained, an amendment must be sent to the HSRO to release the informed consent forms so that recruitment

may begin.

This study must be conducted in accordance with IRB approval and you must use the documents as modified by the IRB. If you do not accept the changes made by the IRB, the study must not be initiated. If the changes are not acceptable, you may withdraw the study or appeal to the IRB. Should you have any questions, please contact Simonnette Thompson, IRB Regulatory Analyst, at (305) 243-9916 or via e-mail at SThompson2@med.miami.edu.

A request to continue this study must be submitted to the HSRO at least **45 days** before IRB approval expires. If this study does not receive continuing IRB approval prior to expiration, all research activities must cease, and may officially be suspended or terminated

All principal investigators must abide by and comply with all policies and procedures for the conduct of human subject research as posted on the HSRO website (<http://www.hsro.miami.edu>)

Sincerely,

Amanda Coltes-Rojas, MPH, CIP
Associate Director
Regulatory Affairs & Educational Initiatives

/cg

cc: IRB File

Guillermo Prado
Stephanie Donahue

EXPEDITED – APPROVAL

April 27, 2009

Guillermo Prado , Ph.D.
University of Miami
Department of Center for Family Studies
Medical Campus, Locator Code: D22

HSRO STUDY NUMBER: **20080117**

STUDY TITLE: **Preventing HIV Risk Behaviors among Hispanic Adolescents**

IRB ACTION DATE: **4/24/2009**

STUDY APPROVAL EXPIRES: **4/23/2010**

On April 24, 2009, an IRB Chair approved the following items under the expedited review process.

APPROVAL INCLUDES:

Continuing Report (CRR006911)

NOTE: Please note that no subjects are to be enrolled until a Certificate of Confidentiality is obtained from the NIH. Once one is obtained, an amendment must be sent to the HSRO to release the informed consent forms so that recruitment may begin.

A request to continue this study must be submitted to the HSRO at least **45 days** before IRB approval expires. If this study does not receive continuing IRB approval prior to expiration, all research activities must cease, and may officially be suspended or terminated.

All principal investigators must abide by and comply with all policies and procedures for the conduct of human subject research as posted on the HSRO website (<http://www.hsro.miami.edu>)

Sincerely,

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Amanda Coltes-Rojas, MPH, CIP
Director
Regulatory Affairs & Educational Initiatives

/vc

cc: IRB File

Guillermo Prado
Stephanie Donahue

Human Subjects Research Office (M809)
PO Box 016960, Miami, Florida 33101
1500 NW 12 Avenue, Suite 1002, Miami, Florida 33136
Tel: 305-243-3195
Fax: 305-243-3328



EXPEDITED – APPROVAL

April 7, 2010

Guillermo Prado, Ph.D.
University of Miami
Department of Epidemiology and Public Health
Center for Family Studies
Medical Campus, Locator Code: D22
Sieron, Room 301
Miami, FL 33136

HSRO STUDY NUMBER: **20080117**
STUDY TITLE: **Preventing HIV Risk Behaviors among Hispanic Adolescents**
IRB ACTION DATE: **4/7/2010**
STUDY APPROVAL EXPIRES: **4/6/2011**
Continuing Report #: [CRR009117](#)
SPONSOR NAME: The Centers for Disease Control and Prevention
FWA #: FWA00002247

On 4/7/2010, an IRB Chair approved the following items under the expedited review process:

APPROVAL INCLUDES:

- Continuing Report (CRR009117)
- Research Materials (*English & Spanish Versions*)

- Primary Parent Informed Consent Form
- Primary Youth Assent Form
- Secondary Family Adult Informed Consent Form
- Secondary Family Parental Informed Consent Form
- Secondary Family Youth Assent Form

NOTE: Translations of IRB approved study documents, including informed consent documents, into languages other than English must be submitted to HSRO for approval prior to use.

A request to continue this study must be submitted to the HSRO at least **45 days** before IRB approval expires. If this study does not receive continuing IRB approval prior to expiration, all research activities must cease, and it may be officially suspended or terminated.

Sincerely,

[This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature]

Amanda Coltes-Rojas, MPH, CIP
Director
Regulatory Affairs & Educational Initiatives

/smh

cc: IRB File

Meghan Calfee
Margaret Arzon
Guillermo Prado