

**HIV Prevention among Latino MSM: Evaluation of a locally developed
intervention**

Attachment 8

**Local IRB Approvals
(Wake Forest University)**

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Scott Rhodes, Ph.D.
PHS - Social Sciences

From: Chair, Institutional Review Board

Date: 5/26/2010

Subject: Expedited Review: IRB00013197
HIV Prevention Among Latino MSM: Evaluation of a locally developed
intervention

This research study qualifies for expedited review under the Federal Regulations [45CFR46.110]. These regulations allow an IRB to approve certain kinds of research involving no more than minimal risk to human subjects. The risks of harm anticipated in the proposed research are not greater than those ordinarily encountered by the general population in daily life or during the performance of routine physical, laboratory, or psychological exams or tests. [45CFR46.102(i)]. Upon review of the research, the IRB finds that this study meets the following expedited review category(s):

Category 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.

IRB approval is for a period of 12 months from 5/26/2010. Please notify the Office of Research when the project is complete.



Richard Weinberg, M.D.

Office of Research
INSTITUTIONAL REVIEW BOARD.

MEMORANDUM

To: Scott Rhodes, Ph.D.
PHS - Social Sciences

From: Chair,
Institutional Review Board

Date: 4/11/2011

Subject: Human Protocol: IRB00013197
HIV Prevention Among Latino MSM: Evaluation of a locally developed intervention

Study Documents:

Protocol Version: Protocol 01-14-11.docx; Informed Consent Version: HOLA en Grupos ICF English 04 01 11.docx (approved), HOLA en Grupos ICF SPANISH 4 1 11.doc (approved)

This is to confirm for your record that the Institutional Review Board reviewed your progress report and consent form, containing compounded HIPAA authorization language, if applicable, for the above-named protocol. IRB approval was activated on 4/9/2011 and will expire on 4/8/2012. If the protocol is to remain active longer, a written request for renewal, together with a summary progress report, and a copy of the current consent form, if applicable, should be submitted to the Board at least one month prior to expiration.

Upon review of the research, the IRB finds that this study is classified as Expedited Category 7.

Based on the information provided, the IRB has determined that HIPAA does not apply to this study.

Please provide a final report to the Board when the project is completed and Board approval can be terminated.

This IRB is in compliance with the requirements in Part 56, Subchapter D, Part 312 of the 21 Code of Federal Regulations published January 27, 1981 and Part 46, Subpart A of 45 CFR published January 26, 1981.



Richard Weinberg, M.D.

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Scott Rhodes, Ph.D.
PHS - Social Sciences

From: Vice Chair, Institutional Review Board

Date: 8/3/2010

Subject: Human Protocol: IRB00013197
HIV Prevention Among Latino MSM: Evaluation of a locally developed intervention
Amendment 1 for IRB Study #IRB00013197

Study Documents:

Protocol Version: Protocol 4-5-10.docx; Informed Consent Version: HOLA en Grupos ICF English 05 11 10.doc (approved)

The amendments listed below have been approved in accordance with HHS regulations for the protection of human research subjects that provides for the expedited review and approval of minor changes in previously approved research [45 CFR 46.110(b)(2)]. This action of the Board does not extend the term of approval for this protocol.

The amendment includes the following:

- Jorge Alonzo added to study team.

This IRB is in compliance with the requirements of Part 56, 21 Code of Federal Regulations published as of April 1994 and Part 46, Subpart A of 45 CFR published January 26, 1981.



Joseph Andrews

Office of Research

INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Scott Rhodes, Ph.D.
PHS - Social Sciences

From: Vice Chair, Institutional Review Board

Date: 9/1/2010

Subject: Human Protocol: IRB00013197
HIV Prevention Among Latino MSM: Evaluation of a locally developed intervention
Amendment 2 for IRB Study #IRB00013197

Study Documents:

Protocol Version: Protocol 4-5-10.docx; Informed Consent Version: HOLA en Grupos ICF English 05 11 10.doc
(approved)

The amendments listed below have been approved in accordance with HHS regulations for the protection of human research subjects that provides for the expedited review and approval of minor changes in previously approved research [45 CFR 46.110(b)(2)]. This action of the Board does not extend the term of approval for this protocol.

The amendment includes the following:

- Changes to study team members.

This IRB is in compliance with the requirements of Part 56, 21 Code of Federal Regulations published as of April 1994 and Part 46, Subpart A of 45 CFR published January 26, 1981.



Scott Rushing

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Scott Rhodes, Ph.D.
PHS - Social Sciences

From: Vice Chair, Institutional Review Board

Date: 1/4/2011

Subject: Human Protocol: IRB00013197
HIV Prevention Among Latino MSM: Evaluation of a locally developed intervention
Amendment 3 for IRB Study #IRB00013197

Study Documents:

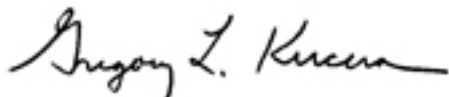
Protocol Version: Protocol 4-5-10.docx; Informed Consent Version: HOLA en Grupos ICF English 05 11 10.doc (approved)

The amendments listed below have been approved in accordance with HHS regulations for the protection of human research subjects that provides for the expedited review and approval of minor changes in previously approved research [45 CFR 46.110(b)(2)]. This action of the Board does not extend the term of approval for this protocol.

The amendment includes the following:

- Changes to study team members.

This IRB is in compliance with the requirements of Part 56, 21 Code of Federal Regulations published as of April 1994 and Part 46, Subpart A of 45 CFR published January 26, 1981.



Gregory Kucera, Ph.D.

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Scott Rhodes, Ph.D.
PHS - Social Sciences

From: Assistant Director, Institutional Review Board

Date: 2/3/2011

Subject: Human Protocol: IRB00013197
HIV Prevention Among Latino MSM: Evaluation of a locally developed intervention
Amendment 4 for IRB Study #IRB00013197

Study Documents:

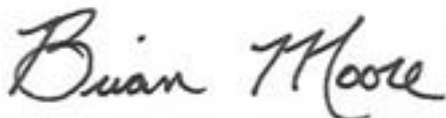
Protocol Version: Protocol 01-14-11.docx; Informed Consent Version: HOLA en Grupos ICF English 12 31 10.doc (approved)

The amendments listed below have been approved in accordance with HHS regulations for the protection of human research subjects that provides for the expedited review and approval of minor changes in previously approved research [45 CFR 46.110(b)(2)]. This action of the Board does not extend the term of approval for this protocol.

The amendment includes the following:

- Protocol revised to reflect change in data collection from 3 times to 2 times (Baseline and 6 months).
- Consent revised to reflect change in data collection from 3 times to 2 times (Baseline and 6 months).
- Application revised to reflect change in data collection from 3 times to 2 times (Baseline and 6 months).

This IRB is in compliance with the requirements of Part 56, 21 Code of Federal Regulations published as of April 1994 and Part 46, Subpart A of 45 CFR published January 26, 1981.



Brian Moore

Office of Research
 INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Scott Rhodes, Ph.D.
 PHS - Social Sciences

From: Assistant Director, Institutional Review Board

Date: 4/19/2011

Subject: Human Protocol: IRB00013197
 HIV Prevention Among Latino MSM: Evaluation of a locally developed intervention
 Amendment 5 for IRB Study #IRB00013197

Study Documents:

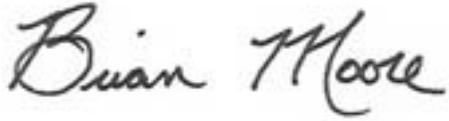
Protocol Version: Appointment card.pdf, complete HOLA en Grupos 11 02 10.docx, HOLA assessment 04 18 11 SPANISH v2.doc, HOLA assessment ENGLISH 04 18 11.doc, HOLA Comparison.pdf, Observers Guide 04 11 11.doc, Protocol 01-14-11.docx, Screening 04 18 11 English.docx, Screening 04 18 11 Spanish.docx, Session Attendance Log.docx, Stay in touch card (2-sided).pdf; Informed Consent Version: HOLA en Grupos ICF English 04 01 11.docx (approved), HOLA en Grupos ICF SPANISH 4 1 11.doc (approved); Advertisements: English flyer 04 15 11.docx, Spanish flyer 04 15 11.docx

The amendments listed below have been approved in accordance with HHS regulations for the protection of human research subjects that provides for the expedited review and approval of minor changes in previously approved research [45 CFR 46.110(b)(2)]. This action of the Board does not extend the term of approval for this protocol.

The amendment includes the following:

- We have changed incorrect compensation in the Consent form. CDC personnel also asked us to removed underlining under Protected Health Information.
-
- We are adding entire HOLA en Grupos intervention curriculum; the comparison curriculum; implementation observer's guide (for fidelity); session attendance log; advertising flyer in English and Spanish; behavioral assessment in English and Spanish; screening form, stay-in-touch cards; and next intervention session reminder cards.

This IRB is in compliance with the requirements of Part 56, 21 Code of Federal Regulations published as of April 1994 and Part 46, Subpart A of 45 CFR published January 26, 1981.

A handwritten signature in black ink that reads "Brian Moore". The signature is written in a cursive style with a large, prominent "M" at the end.

Brian Moore

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Scott Rhodes, Ph.D.
PHS - Social Sciences

From: Assistant Director, Institutional Review Board

Date: 6/2/2011

Subject: Human Protocol: IRB00013197
HIV Prevention Among Latino MSM: Evaluation of a locally developed intervention
Amendment 6 for IRB Study #IRB00013197

Study Documents:

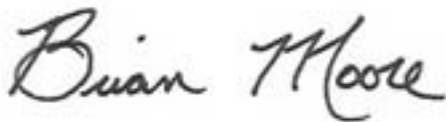
Protocol Version: Appointment card.pdf, complete HOLA en Grupos 11 02 10.docx, HOLA assessment 04 18 11 SPANISH v2.doc, HOLA assessment ENGLISH 04 18 11.doc, HOLA Comparison.pdf, Observers Guide 04 11 11.doc, Protocol 01-14-11.docx, Screening 04 18 11 English.docx, Screening 04 18 11 Spanish.docx, Session Attendance Log.docx, Stay in touch card (2-sided).pdf; Informed Consent Version: HOLA en Grupos ICF English 05 26 11 docx.docx (approved), HOLA en Grupos ICF SPANISH 05 26 11.doc (approved); Advertisements: English flyer 04 15 11.docx, Spanish flyer 04 15 11.docx

The amendments listed below have been approved in accordance with HHS regulations for the protection of human research subjects that provides for the expedited review and approval of minor changes in previously approved research [45 CFR 46.110(b)(2)]. This action of the Board does not extend the term of approval for this protocol.

The amendment includes the following:

- Consent form revision per CDC request: "payment, compensation" changed to "Token of appreciation."

This IRB is in compliance with the requirements of Part 56, 21 Code of Federal Regulations published as of April 1994 and Part 46, Subpart A of 45 CFR published January 26, 1981.



Brian Moore

Office of Research
INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Stacy Duck
PHS - Social Sciences

From: Chair, Institutional Review Board

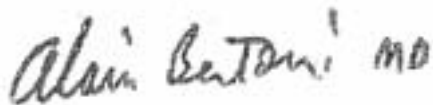
Date Approved: 3/1/2011

Subject: Expedited Review: IRB00015789
HIV Prevention Among Latino MSM: Evaluation of a locally developed
intervention

This research study qualifies for expedited review under the Federal Regulations [45CFR46.110]. These regulations allow an IRB to approve certain kinds of research involving no more than minimal risk to human subjects. The risks of harm anticipated in the proposed research are not greater than those ordinarily encountered by the general population in daily life or during the performance of routine physical, laboratory, or psychological exams or tests. [45CFR46.102(i)].

Upon review of the research, the IRB finds that this study is classified as Expedited Category 7.

IRB approval is for a period of 12 months from 1/9/2011. Please notify the Office of Research when the project is complete.



Alain Bertoni, M.D.

Office of Research
 INSTITUTIONAL REVIEW BOARD

MEMORANDUM

To: Stacy Duck
 PHS - Social Sciences

From: Assistant Director, IRB

Date: 4/19/2011

Subject: Human Protocol: IRB00015789
 HIV Prevention Among Latino MSM: Evaluation of a locally developed intervention
 Amendment 1 for IRB Study #IRB00015789

Study Documents:

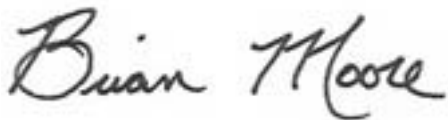
Protocol Version: Appointment card.pdf, complete HOLA en Grupos 11 02 10.docx, HOLA assessment 04 18 11 SPANISH v2.doc, HOLA assessment ENGLISH 04 18 11.doc, HOLA Comparison.pdf, Observers Guide 04 11 11.doc, Protocol 01-14-11 redlined.docx, Protocol 01-14-11.docx, Screening 04 18 11 English.docx, Screening 04 18 11 Spanish.docx, Session Attendance Log.docx, Stay in touch card (2-sided).pdf; Informed Consent Version: HOLA en Grupos ICF English 04 17 11.docx (approved), HOLA en Grupos ICF SPANISH 04 17 11.doc (approved); Advertisements: English flyer 04 15 11.docx, Spanish flyer 04 15 11.docx

The amendments listed below have been approved in accordance with HHS regulations for the protection of human research subjects that provides for the expedited review and approval of minor changes in previously approved research [45 CFR 46.110(b)(2)]. This action of the Board does not extend the term of approval for this protocol.

The amendment includes the following:

- We have changed incorrect compensation in the Consent form . CDC personnel also asked us to removed underlining under Protected Health Information.
- We are adding entire HOLA en Grupos intervention curriculum; the comparison curriculum; implementation observer's guide (for fidelity); session attendance log; advertising flyer in English and Spanish; behavioral assessment in English and Spanish; screening form, stay-in-touch cards; and next intervention session reminder cards.
- We also have included the most up-to-date protocol that reflects the protocol previously submitted and approved for study IRB00013197 (PI: RHODES), this study's counterpart.

This IRB is in compliance with the requirements of Part 56, 21 Code of Federal Regulations published as of April 1994 and Part 46, Subpart A of 45 CFR published January 26, 1981.

A handwritten signature in black ink that reads "Brian Moore". The signature is written in a cursive style with a large, prominent 'B' and 'M'.

Brian Moore