



THE UNIVERSITY OF NEW MEXICO
HEALTH SCIENCES CENTER

Human Research Review Committee
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25-Mar-2008

McClain, Catherine, M.D.
Pediatrics Center for Development

SUBJECT: HRRC Approval of Research - Amendment
HRRC#: 06-001
Study: Evaluation of the "I Can Do It, You Can Do It" Program
Type of Review: Expedited Review
Approval Date: 25-Mar-2008
Expiration Date: 12-Dec-2008

Dear Dr. McClain:

The Human Research Review Committee (HRRC) has approved* the above mentioned research protocol action based on review of the following:
Amendment Form dated 03/19/08 Protocol Amendment, v 03/19/08
Informed Consent letter v 03/19/08

Consent Decision:
Waived the requirement to obtain a signed consent form

VA Studies Only:
Not applicable.

This study is approved to enroll only the number of subjects listed in the application, current protocol and consent form(s). If the PI wants to enroll additional subjects, it is the responsibility of the PI to submit an Amendment/Change to the HRRC before the approved number of enrolled subjects is exceeded. If increased enrollment is requested the application, protocol and/or consent form(s) must also be amended to include the new target.

When consent is required, it is the responsibility of the Principal Investigator (PI) to ensure that ethical and legal informed consent has been obtained from all research participants. A date stamped original of the HRRC approved consent form(s) is attached to this correspondence, and copies should be used for consenting participants during the above noted approval period. If HIPAA Authorization is required, the HIPAA Authorization version noted above should be signed in conjunction with the consent form.

Sincerely,



Mark Holdsworth, Pharm.D., BCOP
Executive Chair
Human Research Review Committee

* Under the provisions of this institution's Federal Wide Assurance (FWA00003255), the HRRC has determined that this proposal provides adequate safeguards for protecting the rights and welfare of the subjects involved in the study and is in compliance with HHS Regulations (45 CFR 46), FDA Regulations (21 CFR 50, 56).