



Scott & White Institutional Review Board  
Federalwide Assurance #FWA00003358  
IRB Registration #IRB00000706

Notification of IRB Action

To: Samuel Forjuoh, MD, DrPH

cc: Vanessa Hoelscher

Project ID: 071304

Title: Implementing and Evaluating Chronic Disease Self Management Models to Reduce Health Disparities in Central Texas

Level of Review: Expedited  
Expedited Review Category: 45 CFR 46.110(b)(1)(2)(7)

Date of Action: 5/9/2013

Type of Action: Approval

Approval Period: 5/9/2013 to 5/8/2014

Continuing Review  
Deadline: 4/8/2014\*

**\*You are responsible for ensuring IRB approval is obtained for the continuation of your project by submitting the required progress report and supporting documentation by the continuing review deadline.**

Item(s) Reviewed: Submission reference number: 037547

1. Continuing Review Submission Form, Version 6.0
2. P20 Project 2 Final Progress Report\_Draft\_4-09-13

Investigator Responsibilities:

- Conduct the study according to the currently approved protocol, institutional policies, and all applicable regulations
- Obtain approval from the IRB of any changes in the research prior to implementation except where necessary to eliminate apparent immediate hazards to human subjects. Such urgent changes must be reported to the IRB within five (5) working days.
- Personally supervise or conduct the research and ensure appropriate delegation of tasks
- Maintain complete and accurate study records and make them available for inspection
- Notify the IRB Office of any external inspections of the research
- Report unexpected adverse outcomes to the IRB within five (5) working days of knowledge of each occurrence
- Assume responsibility for initial and continuing review of the research by the IRB

IRB Responsibilities:

- Review and have authority to approve, require modifications in or disapprove all research activities
- Ensure all requirements for approval of research are satisfied in accordance with federal regulations
- Report any serious or continuing non-compliance by investigators to the appropriate institutional officials, the Office for Human Research Protections, the Food and Drug Administration and any other appropriate regulatory agencies
- Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects
- Determine that all criteria for IRB approval of research are met as stipulated in the federal regulations
- Require that information given to subjects as part of informed consent is in accordance with federal regulations
- Conduct continuing review of research at intervals appropriate to the degree of risk but not less than once per year, including the authority to observe or have a third party observe the research

Signature applied by Matt Ridley on 05/09/2013 08:03:30 AM CDT

Authorized Scott & White IRB Representative