

POLICY & PROCEDURE



TITLE: Participation in Research Projects				
Scope/Purpose: To protect and educate potential participants in clinical or sociological research projects.				
Division/Department: All HealthPoint Clinics			Policy/Procedure #:	
Original Date: 8/14/2010			<input type="checkbox"/> New <input checked="" type="checkbox"/> Replacement for: Same	
Date Reviewed:	Date Revised:	Implementation:	CPIC Approved:	Board Approved:
	12/23/2013			
Responsible Party: Director Compliance/QA				

DEFINITIONS:

Institutional Review Board (IRB)

It is a specially constituted review body established or designated by an entity to protect the rights and welfare of human subject research. It is responsible for the review of human subject research and the review of requests for release of data, including Protected Health Information (PHI).

POLICY:

Texas Department of State and Health Services (DSHS) requires that all proposed human subject research which would involve DSHS clients or data and/or specimens in the possession of DSHS, regardless of the research funding source, will be reviewed by an Institutional Review Board (IRB) that is either sponsored or approved by DSHS.

For clinical or sociological research using clients under DSHS Family Planning or PHC/EPHC as subjects, HealthPoint must obtain prior approval from the agency Institutional Review Board or the Texas Department of State Health Services Institutional Review Board #1(IRB).

If approval is provided through the agency IRB, documentation of approval must be submitted to the Preventive and Primary Care Unit (PPCU) prior to implementation of the research project. The agency is not required to seek approval from the DSHS IRB in this situation.

Research projects in the areas of mental health, mental retardation, and substance abuse research must be approved by the agency IRB or Texas Department of State Health Services Institutional Review Board #2.

PROCEDURE:

Approval through Texas Department of State Health Services IRB:

- A. HealthPoint representative will contact the appropriate DSHS Program Contact. The contact list is available at www.dshs.state.tx.us/irb/applirb.shtm
- B. The completed application (available at the same website) is submitted to the appropriate DSHS Program Contact for review and signature.
- C. The Program Contact will forward the signed application to the IRB Office for consideration and approval.

RELATED POLICY:

REFERENCES:

DSHS Family Planning Services 2014 Policy Manual
DSHS Primary Health Care Program 2014 Policy Manual
DSHS Expanded Primary Health Care Program 2014 Policy Manual
US Department of Health and Human Services
Office of Human Research Protection

REQUIRED BY:

Title 45 Code of Federal Regulations Part 46

ATTACHMENTS/ENCLOSURES:

POLICY/PROCEDURE TRACKING FORM (to be added as last page of each P&P for documentation of changes)

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Date of Revision		Description of Changes		
12/23/13		Updated to new format; Updated to 2014 DSHS standards regarding Family Planning, PHC and EPHC.		