

**TEXAS DEPARTMENT OF STATE HEALTH SERVICES
CENTRAL OFFICE INSTITUTIONAL REVIEW BOARD
CHECKLIST FOR RESEARCH PROTOCOL**

Protocol #: _____ - _____ - _____

Basic Elements of Research Protocol	
Page # where located	Elements
	Title of Study
	Study Investigators and Affiliations
	Background and Significance
	Purpose of the Study
	Study Methods and Procedures
	Number of Subjects
	Criteria for Inclusion/Exclusion (explain and justify) Document if any subjects from vulnerable populations
	Method of Subject Identification and Recruitment
	Procedure for Explaining and Obtaining Informed Consent
	Procedures for Data Storage and Maintenance of Confidentiality
	Potential Risks to Subjects (if possible, estimate probability of given harm, its severity, & potential reversibility)
	Procedures to Minimize Risks
	Potential Benefits To Participants To Society
	Description of Incentives to Participation or Compensation
	Data Analysis Plans
Additional Requirements, as appropriate	
	Emergency Care and Compensation for Research-Related Injury (necessary if greater than minimal risk)
	Methods for monitoring data collected to ensure safety of subjects
	Alternative treatments available to research subjects who are patients
	Additional protections and safeguards for vulnerable populations

Additional Requirements from TDMHMR Research Rule	
	Process for recruiting and screening subjects at the facility
	Number of subjects to be enrolled at the facility
	Process for and level of clinical monitoring of subjects throughout the research period
	Justification of research design and proposed analyses
	Scientific rationale for targeting the proposed population
	Process for assessing capacity to consent to research (if greater than minimal risk) Describe who will conduct assessment and nature of assessment
	Method and description of procedure to maintain continuity of care if subject discharged from the facility