TCH IRB NEW PROTOCOL COVER SHEET

IRB #: _____
Date: _____

IRB USE ONLY
Date Received by IRB
(Date Stamp):

REQUIREMENT (NOTE: Materials must be submitted at least 21 days prior to meeting; meetings held 2nd Tues. of each month. Materials submitted without the required signatures will be returned as incomplete.)	**Initial**
-- Obtained TCH protocol # from IRB Office (585-2298 or 585-2742).	
-- Protocol attached, ***original plus 2 copies*** • The DHHS-approved sample consent document (when one exists) (original plus 2 copies) • The complete DHHS-approved protocol (when one exists) (original plus 2 copies)	
-- TCH Study Application - ***original plus 17 copies***.	
-- Informed Consent in TCH format written at 6th grade reading level (see specific guidelines). – ***original plus 17 copies***	
-- Waiver of Informed Consent or Waiver of Documentation of Informed Consent, when applicable – ***original plus 17 copies***	
-- Have investigator or designee attend the IRB meeting to present the protocol. (Call 585-2298 to obtain approximate time to present.)	
-- TCH Financial Disclosure forms are included for all investigators (PI and co-investigators) – ***originals plus 17 copies*** *****We ONLY accept Sponsor financial disclosure forms if the amount listed is $10,000 or below*****	
-- HIPAA Request for Partial Waiver is included and signed by the PI, when applicable. ***original plus 17 copies***	
-- Investigational Drug Data or Device Data sheet, signed by PI included, when applicable. **Original**	
-- Advertising/Recruitment Materials are attached, when applicable – ***original plus 17 copies***	
-- Investigator's Brochure, when applicable – ***original plus 2 copies***	
-- CITI course has been completed within last 3 years by all investigators – ***1 copy of transcript***	
-- Any Relevant Grant Applications – ***1 copy***	

DOCUMENTS REQUIRED WITH PROTOCOL SUBMISSION:	
Advertising Materials, if applicable: Original +17	Waiver of Informed Consent, if applicable: Original + 17
Financial Disclosure Forms: Originals + 17	Waiver of Documentation of Informed Consent: Original + 17
HIPPA Partial Waiver, if applicable: Original +17	Study Application: Original +17
Informed Consent: Original + 17	Protocol: Original + 2
Investigational Drug Data Sheet, if applicable: Original	CITI Course Transcript: 1 copy for each investigator
Investigator's Brochure, if applicable: Original + 2	Relevant Grant Applications: 1 copy