

Protocol Details

Protocol #	2005P001108	PI	Thiele, Elizabeth	Title	Genotype and Phenotype in Tuberous Sclerosis Complex
Version		Version Date	5/20/2005	Sponsor	INTERNAL
Overall Status	Active, Ongoing	Approval Date	10/14/2014	Expiration Date	10/05/2016
DateReceived	5/20/2005	Administrator	Granadeno, Monica	Email	MGRANADENO@PARTNERS.ORG
Phone	617-424-4105	Institution	MGH	Last Modified	08/14/2015
Proposal Number	NA	Fund Number	NA	Type Of Protocol	Health / Medical Records
Risk	RISK_MINIMAL				

Initial Review Summary | 1

Date Received	Board	Review Type	Meeting Date	Review Status	Status Date	Response Date
5/20/2005	IRB	Expedited	7/12/2005	Approved	6/9/2005	
5/20/2005	IRB	Expedited		Deferred	5/25/2005	6/3/2005
5/20/2005	IRB	Expedited		Pending	5/24/2005	

Continuing Reviews | 18 Total | 0 Pending

CR #	Date Received	Project Status	Board	Review Type	Meeting Date	Review Status	Status Date	Response Date
CR8	7/8/2014	Ongoing Data Collection	IRB	Expedited		Approved	10/14/2014	
CR8	7/8/2014	Ongoing Data Collection	IRB	Expedited		Pending	10/14/2014	
CR8	7/8/2014	Ongoing Data Collection	IRB	Expedited		Requires Modification	9/16/2014	10/12/2014
CR8	7/8/2014	Ongoing Data Collection	IRB	Expedited		Pending	9/15/2014	
CR7	8/14/2012	Ongoing	IRB	Expedited		Approved	10/5/2012	
CR7	8/14/2012	Ongoing	IRB	Expedited		Pending	8/14/2012	
CR6	8/30/2010	Ongoing	IRB	Expedited		Approved	10/20/2010	
CR6	8/30/2010	Ongoing	IRB	Expedited		Pending	8/30/2010	
CR5	10/16/2009	Ongoing	IRB	Expedited	12/8/2009	Approved	11/17/2009	
CR5	10/16/2009	Ongoing	IRB	Expedited		Pending	10/16/2009	
CR4	10/16/2008	Ongoing	IRB	Expedited	1/13/2009	Approved	12/22/2008	
CR4	10/16/2008	Ongoing	IRB	Expedited		Pending	10/16/2008	
CR3	12/27/2007	Ongoing	IRB	Expedited	1/29/2008	Approved	1/7/2008	
CR3	12/27/2007	Ongoing	IRB	Expedited		Pending	12/27/2007	
CR2	2/14/2007	Ongoing	IRB	Expedited	3/27/2007	Approved	3/5/2007	
CR2	2/14/2007	Ongoing	IRB	Expedited		Pending	2/14/2007	
CR1	4/5/2006	Ongoing	IRB	Expedited	5/23/2006	Approved	4/27/2006	
CR1	4/5/2006	Ongoing	IRB	Expedited		Pending	4/5/2006	

Amendments | 86 Total | 0 Pending

AME #	Sponsor AME #	Date Received	Board	Review Type	Review Status	Status Date	Response Date
AME46		7/28/2015	IRB	Administrative	Noted	7/28/2015	
AME45		3/2/2015	IRB	Administrative	Noted	3/2/2015	
AME44		2/26/2015	IRB	Administrative	Noted	2/26/2015	
AME43		2/11/2015	IRB	Expedited	Approved	3/31/2015	
AME43		2/11/2015	IRB	Expedited	Pending	3/31/2015	
AME43		2/11/2015	IRB	Expedited	Requires Modification	2/24/2015	3/30/2015
AME43		2/11/2015	IRB	Expedited	Pending	2/24/2015	
AME43		2/11/2015	IRB	Expedited	Requires Modification	2/22/2015	2/23/2015
AME43		2/11/2015	IRB	Expedited	Pending	2/13/2015	
AME42		2/12/2015	IRB	Administrative	Noted	2/12/2015	
AME41		10/8/2014	IRB	Expedited	Approved	10/9/2014	
AME40		9/23/2014	IRB	Expedited	Approved	9/24/2014	
AME39		9/23/2014	IRB	Expedited	Withdrawn	10/27/2014	
AME39		9/23/2014	IRB	Expedited	Requires Modification	9/24/2014	
AME38		7/7/2014	IRB	Expedited	Approved	7/8/2014	
AME37		6/30/2014	IRB	Expedited	Approved	6/30/2014	
AME36		10/30/2013	IRB	Expedited	Approved	11/1/2013	
AME35		5/5/2013	IRB	Expedited	Approved	5/7/2013	
AME34		3/19/2013	IRB	Expedited	Approved	3/19/2013	
AME34		3/19/2013	IRB	Expedited	Pending	3/19/2013	
AME33		10/2/2012	IRB	Expedited	Approved	10/2/2012	
AME33		10/2/2012	IRB	Expedited	Pending	10/2/2012	
AME32		4/30/2012	IRB	Expedited	Approved	4/30/2012	
AME32		4/30/2012	IRB	Expedited	Pending	4/30/2012	
AME31		6/29/2011	IRB	Expedited	Approved	6/29/2011	
AME31		6/29/2011	IRB	Expedited	Pending	6/29/2011	
AME30		5/26/2011	IRB	Expedited	Approved	5/26/2011	
AME30		5/26/2011	IRB	Expedited	Pending	5/26/2011	
AME29		5/23/2011	IRB	Expedited	Approved	5/23/2011	
AME29		5/23/2011	IRB	Expedited	Pending	5/23/2011	
AME28		5/18/2011	IRB	Expedited	Approved	5/18/2011	
AME28		5/18/2011	IRB	Expedited	Pending	5/18/2011	
AME27		5/13/2011	IRB	Expedited	Approved	5/13/2011	
AME27		5/13/2011	IRB	Expedited	Pending	5/13/2011	
AME26		4/22/2011	IRB	Expedited	Approved	4/22/2011	
AME26		4/22/2011	IRB	Expedited	Pending	4/22/2011	
AME25		1/18/2011	IRB	Expedited	Approved	1/18/2011	
AME25		1/18/2011	IRB	Expedited	Pending	1/18/2011	

AME24		12/6/2010	IRB	Expedited	Approved	12/6/2010	
AME24		12/6/2010	IRB	Expedited	Pending	12/6/2010	
AME23		10/12/2010	IRB	Expedited	Approved	10/12/2010	
AME23		10/12/2010	IRB	Expedited	Pending	10/12/2010	
AME22		9/15/2010	IRB	Expedited	Approved	9/16/2010	
AME22		9/15/2010	IRB	Expedited	Pending	9/15/2010	
AME21		7/6/2010	IRB	Expedited	Approved	7/7/2010	
AME21		7/6/2010	IRB	Expedited	Pending	7/6/2010	
AME20		4/27/2010	IRB	Expedited	Approved	5/4/2010	
AME20		4/27/2010	IRB	Expedited	Pending	4/27/2010	
AME19		1/29/2010	IRB	Expedited	Approved	2/1/2010	
AME19		1/29/2010	IRB	Expedited	Pending	1/29/2010	
AME18		1/29/2010	IRB	Expedited	Withdrawn	3/30/2011	
AME18		1/29/2010	IRB	Expedited	Pending	1/29/2010	
AME17		1/29/2010	IRB	Expedited	Approved	2/1/2010	
AME17		1/29/2010	IRB	Expedited	Pending	1/29/2010	
AME16		12/21/2009	IRB	Expedited	Approved	2/23/2010	
AME16		12/21/2009	IRB	Expedited	Pending	12/21/2009	
AME15		9/10/2009	IRB	Expedited	Approved	7/19/2010	
AME15		9/10/2009	IRB	Expedited	Pending	9/10/2009	
AME14		3/2/2009	IRB	Expedited	Approved	3/12/2009	
AME14		3/2/2009	IRB	Expedited	Pending	3/2/2009	
AME13		11/6/2008	IRB	Expedited	Approved	11/7/2008	
AME13		11/6/2008	IRB	Expedited	Pending	11/6/2008	
AME12		9/30/2008	IRB	Expedited	Approved	10/2/2008	
AME12		9/30/2008	IRB	Expedited	Pending	9/30/2008	
AME11		1/11/2008	IRB	Expedited	Approved	1/15/2008	
AME11		1/11/2008	IRB	Expedited	Pending	1/11/2008	
AME10		12/27/2007	IRB	Expedited	Approved	1/7/2008	
AME10		12/27/2007	IRB	Expedited	Pending	12/27/2007	
AME9		7/13/2007	IRB	Expedited	Approved	7/24/2007	
AME9		7/13/2007	IRB	Expedited	Pending	7/13/2007	
AME8		6/28/2007	IRB	Expedited	Approved	6/29/2007	
AME8		6/28/2007	IRB	Expedited	Pending	6/28/2007	
AME7		6/11/2007	IRB	Expedited	Approved	6/11/2007	
AME7		6/11/2007	IRB	Expedited	Pending	6/11/2007	
AME6		4/11/2007	IRB	Expedited	Approved	4/19/2007	
AME6		4/11/2007	IRB	Expedited	Pending	4/11/2007	
AME5		3/13/2007	IRB	Expedited	Approved	3/19/2007	
AME5		3/13/2007	IRB	Expedited	Pending	3/13/2007	
AME4		2/14/2007	IRB	Expedited	Approved	3/5/2007	

AME4		2/14/2007	IRB	Expedited	Pending	2/14/2007	
AME3		9/15/2006	IRB	Expedited	Approved	9/29/2006	
AME3		9/15/2006	IRB	Expedited	Pending	9/15/2006	
AME2		8/4/2006	IRB	Expedited	Approved	8/4/2006	
AME2		8/4/2006	IRB	Expedited	Pending	8/4/2006	
AME1		7/13/2005	IRB	Expedited	Approved	7/15/2005	
AME1		7/13/2005	IRB	Expedited	Pending	7/13/2005	

Other Events | 0 Total | 0 Pending

OE #	Event Type	Date Received	Board	Review Type	Review Status	Status Date	Response Date
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Approval Notes

Transaction	Notes
AME35	Amended to: Add Christina Anagnos to the study staff.
AME36	Study Staff Added: Rahul Sheth, Co-Investigator and Thomas Walker, Co-Investigator
AME37	Study Staff Added: Joshua Chang, Intern/Student
AME38	Study Staff Removed: Margaux Black, Khyati Brahmabhatt, Kai Cao, Michael Kurtz, Anna Larson, Adam Numis, Laura Ortiz-Teran, Annabel Raby, Robin Ryther and Elmer Van Esghen
AME40	Study Staff Removed: Jason Johnson
AME41	Study Staff Added: Gloria Salazar, Co-Investigator
AME43	Application, Section 5: The end date appears 1/3000 appears to be a typo. Please correct this. Note that you may use data through 7 years into the future or you may keep this a retrospective study collecting only through the current date. Please also note this change of date in the text of your proposed amendment changes.
AME43	The text of your amendment states that the end date for clinical data will be 2/2022. Please revise Section 5 of your application to reflect this.
AME43	Amended to: <ul style="list-style-type: none"> Enroll BWH sporadic LAM patients to, allowing the PI to review health/medical records including demographic information and radiology scans. Change the Medical Records review end date from 01/3000 to 02/2022.
CR8	<ul style="list-style-type: none"> Anyone conducting human subject research is required to complete the University of Miami Collaborative IRB Training Initiative (CITI) Course, and then the Refresher Course every three years. Jason Johnson cannot participate in the study until he has completed and passed the applicable Biomedical CITI course. Please have him complete the course as soon as possible and submit a PI response document attaching his certificate OR remove him from the study staff with a staff amendment. You can find instructions on how to register and complete the certifications on our web page: http://healthcare.partners.org/phsirr/aboutciti.htm
CR8	Approved for Ongoing Data Collection.