Display of Minutes History

Protocol ID : 13-005419

Protocol Title: Diagnostic specificity of hepatic sinusoidal dilatation

Administrative Inquiry

Committee Name - (Project ID) - (Minute Status)	PR13-005419-01
Meeting Date	9/28/2016
Decision	
Agenda Type	
Link to:	View/Print Continuing Review
Letter to PI	Continuation of the above referenced study is approved by expedited review procedures (45 CFR 46.110, item 5). This approval is valid for a period of 3 year(s). The Reviewer determined the research continues to pose no more than minimal risk to subjects. The Reviewer determined that this research continues to satisfy the requirements of 45 CFR 46.111. AS THE PRINCIPAL INVESTIGATOR OF THIS PROJECT, YOU ARE RESPONSIBLE FOR THE FOLLOWING RELATING TO THIS STUDY: 1) When applicable, use only IRB approved materials which are located under the documents tab of the IRBe workspace. Materials include consent forms, HIPAA, questionnaires, contact letters, advertisements, etc. 2) Submission to the IRB of any modifications to approved research along with any supporting documents for review and approval prior to initiation of the changes. 3) Submission to the IRB of all Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO). 4) Compliance with Mayo Clinic Institutional Policies.
Additional minutes	

Committee Name - (Project ID) - (Minute Status)	Mod13-005419-03
Meeting Date	8/22/2016
Decision	
Agenda Type	
Link to:	View/Print Modification
Letter to PI	A personnel modification for the above referenced study has been submitted electronically. The following personnel changes have been made.

People Added	Location	Role	Edit	Consent	Notify	LabResults

	<table><tr><td>People Added</td><td>Location</td><td>Role</td><td>Edit</td><td>Consent</td><td>Notify</td><td>LabResults</td></tr><tr><td>Dharma Sunjaya</td><td>Mayo Clinic in Rochester, MN</td><td>Co-Investigator</td><td>yes</td><td>yes</td><td>yes</td><td>yes</td></tr></table>
Additional minutes	

Committee Name - (Project ID) - (Minute Status)	Mod13-005419-01
Meeting Date	7/27/2016
Decision	
Agenda Type	
Link to:	View/Print Modification
Letter to PI	A personnel modification for the above referenced study has been submitted electronically. The following personnel changes have been made. <table><tr><td>People Added</td><td>Location</td><td>Role</td><td>Edit</td><td>Consent</td><td>Notify</td><td>LabResults</td></tr><tr><td>Douglas Simonetto</td><td>Mayo Clinic in Rochester, MN</td><td>Co-Investigator</td><td>yes</td><td>yes</td><td>no</td><td>yes</td></tr></table>
Additional minutes	

Committee Name - (Project ID) - (Minute Status)	13-005419
Meeting Date	10/11/2013
Decision	Approve
Agenda Type	
Link to:	View/Print Study
Letter to PI	The above referenced application is approved by expedited review procedures (45 CFR 46.110, item 5). **This approval is valid for a period of 3 years.** The Reviewer conducted a risk-benefit analysis, and determined the study constitutes minimal risk research. The Reviewer determined that this research satisfies the requirements of 45 CFR 46.111. The Reviewer approved waiver of the requirement to obtain informed consent in accordance with 45 CFR 46.116 as justified by the Investigator, and waiver of HIPAA authorization in accordance with applicable HIPAA regulations. AS THE PRINCIPAL INVESTIGATOR OF THIS PROJECT, YOU ARE RESPONSIBLE FOR THE FOLLOWING RELATING TO THIS STUDY.

	1) When applicable, use only IRB approved materials which are located under the documents tab of the IRBe workspace. Materials include consent forms, HIPAA, questionnaires, contact letters, advertisements, etc. 2) Submission to the IRB of any modifications to approved research along with any supporting documents for review and approval prior to initiation of the changes. 3) Submission to the IRB of all Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO). 4) Compliance with Mayo Clinic Institutional Policies.
Additional minutes	

Close