



# Continuing Review Resource Guide for Research Personnel and

# Principal Investigators

**Purpose:** To provide guidance from data entry to IRB submission and determination letter dissemination.

Audience: Research Personnel and Principal Investigators

**Summary:** This resource guide focuses on the continuing review application from data entry to IRB submission and outcome letter dissemination. The information provided in this resource guide contains helpful information for both research personnel and principal investigators. Please consult the Table of Contents below to find the information you need.

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## **Dashboard Information:**

- 1. When you log into IRBManager, your dashboard will appear. The information on your dashboard can be subdivided into four categories:
  - a) Actions Sidebar: Here, you can start x-forms<sup>1</sup> or go to your recently reviewed items. You can also see the progress status of all your x-forms.
  - b) My Projects Box: Under 'My Projects,' you will see more information on your projects<sup>2</sup>, x-forms, and study events<sup>3</sup>.
  - c) Notices Box: Important IRB information can be found here.
  - d) My Projects Table: The table is a listing of all your active research studies. By clicking on the blue study link, you will be directed to the study profile.

a) ACTIONS SIDEDA				b) My Projects Box		c	) Notice	<mark>s Box</mark>		
Adventist	Home					Find Proje	ct (Ctrl+	Q)		٩
<b>HealthCare</b>	4y Projects	5		т	ake	a tour F	lelp Te	st's Settin	igs Sign o	off
Actions	Projects (	•				tices				
IRB				tive Projects and <u>6 total</u> Projects.		ase contact t RB@adventi				0
Member/Consultant/Invite Confidentiality				nd <u>6 total</u> Projects.	que	stions.			, i	
Statement				in the next 90 days. 019-TEST-SGMC.	Tha	nk you.				
Reliance Agreement			ire is <u>z</u>	019-1E51-5GMC.						
Start xForm	xForms (1	0 Active)								
Show Sponsor IDs	<ul> <li>You have</li> </ul>	e <u>2 unsubmit</u>	ted xFo	rms.						
Recent Items	<ul> <li>You have</li> </ul>	e <u>8 xForms</u> be	eing pro	ocessed at a later stage.						
2019-TEST-SGMC 2017-07-SGMC	Events (19	9 Open)								
2017-06-WAH	Only show	events where	I am:	Y						
WA-2013-09-WAH	You have	e <u>9 Amendme</u>	nt eve	nts.						
Messages		e <u>6 Continuin</u>								
Welcome to IRBManager	_	e <u>1 Deviation</u>								
at Adventist HealthCare	-	e <u>1 Initial Rev</u> 2 Reportabl		ents. erse Event events.						
	_	e 19 Total Ope	-							
My Docs & xForms 0 Attachments	- Tou nure	<u>15 rotur opt</u>								
3 xForms	My Project	ts (6 Active)								T
	Project 👗	site *	<b>РІ</b> <sup>\$</sup>	Title	¢	Expires +	Status		leference loc(s)	¢
	2017-07- SGMC	Shady Grove Medical Center	Test PI, MD	A Randomized, Double Blind Controlled Factorial Clinical Trial of Edetate Disodium Based Chelation and High-Dose Oral Vitamins and Minerals to Prevent Recurrent Cardiac Events in Diabetic Patients With a Prior Myocardial Infaction		02/13/2019	Closed Enrolln			

Project	Site +	PI <sup>‡</sup>	Title	Expire	es 🍦	Status 🔶 🕈	Doc(s)
2017-07- SGMC	Shady Grove Medical Center	Test PI, MD	A Randomized, Double Blind Controlled Factorial Clinical Trial of Edetate Disodium- Based Chelation and High-Dose Oral Vitamins and Minerals to Prevent Recurrent Cardiac Events in Diabetic Patients With a Prior Myocardial Infaction	02/13/	2019	Closed to Enrollment	
2018-07- WAH	Washington Adventist Hospital	Test PI, MD	EnSite Precision Observational Study	01/07/	2020	Pending IRB Review	
2018-08- WAH	Washington Adventist Hospital	Test PI, MD	CREST-H			Pending IRB Review	
2019- TEST- SGMC	Shady Grove Medical Center	Test PI, MD	Best Drug/Device Study Ever	02/11/	2019	Pending IRB Review	
Test-AHC	Adventist HealthCare	Test PI, MD	Test Study	11/08/	2019	Active/Enrolling	
WA-2013- 09-WAH	Washington Adventist Hospital	Test PI, MD	GraftMaster® RX Coronary Stent Graft System	07/11/	2019	Active/Enrolling	

d) My Projects Table



# **Study Profile Information:**

2. Once you are on the study profile, you may begin submitting x-forms. To submit a x-form, go to the actions side bar and click 'Start xForm.' Afterwards, a list of available x-forms will populate. Choose the "Continuing Review Application".

Adventist	Home						Find Pr	oject (Ctrl+Q)	
<b>HealthCare</b>	Project 2019-TEST	-SGM	C (IRB	:)			Help	Test's Sett	ings Sign
	▼ Project								
Actions	Proj	iect: 2	2019-1	EST	Sponsor(s):	Duke Clinical Re	esearch Insti	tute (Primary)	
Send EMail	Commit	tee: A	Adventi	st HealthCare IRB	Sponsor ID:				
Start xForm	Categ	ory:			Grants:	TEST			
xForms (0)	Departm	ent: (	Critical	Care					
Done	Agent Ty	pes: (	Device	• Drug	CRO:				
Recent Items	Г	itle: E	Best Dr	ug/Device Study Ever	Year:	2018			
	Expedited Categ	ory: 6	5, 1B						
2019-TEST-SGMC 2017-07-SGMC	Comme	nts:							
2017-06-WAH	Project-Site								
WA-2013-09-WAH	Site	(5): 5	SGMC -	Shady Grove Medical Center and others	PI:	Test PI, MD			
Messages	Sta	tus: P	Pending	IRB Review	Additional:	N			
Welcome to IRBManager	Appro	val: F	ebruar	y 13, 2018 for 11 months	Expiration:	February 11, 2	2019		
at Adventist	Initial Appro	val: F	ebruar	y 13, 2018	Other Expirations:				
HealthCare	ICF Version D	ate: 1	10/25/2	2018	Number of				
My Docs & xForms					Subjects/Charts:				
0 Attachments	Comme								
2 xForms	Project-Site Con	ntacts	(2)						
	Name				* Role				
	Elizabeth Carroll, M	РН			Sub-Investigator				
	Maria Halaguena				Research Coordinator				
	Events (3)								
	Event +	Att	FE	Instance/UDF		\$	Start 4	Complete	Last Mtg
	Amendment	1					01/16/201	9	
	Amendment	5					01/14/2019	9	
	Continuing Review	6					01/11/201	2	

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## Start a Continuing Review Application:

 Once you select the continuing review application, the Study Header page will populate. The Study Header page contains information on the IRB study number, protocol site<sup>4</sup>, study expiration date, principal investigator, and agent type<sup>5</sup>. The creating user<sup>6</sup> will be the person who started the x-Form.

	b) Collaborators a) Header Drop Down		
Adventist HealthCare Continuing Review Header	P Collaborators Header	Page 1 of 7  Next	]
Continuing Review results	Creating User Marla Halaguena Email: mhalague@adventisthealthcare.com Business: 301-3	Add Note View Audit	
	TRB Study Number 2018-08	Add Note View Audit	
	Study Name CREST-H Study Expiration Date	Add Note View Audit	
	3/19/2018 for 12 months - Expiration: 3/18/2019 Principal Investigator	Add Note View Audit	
	Test PI, MD Email: mhalague@terpmail.umd.edu Phone:		
	Organizational Entity WAH - Washington Adventist Hospital	Add Note View Audit	
	Agent Type: Device	Add Note View Audit	
	Next Save for Later More -		

- a) The header drop down allows you to skip from one page to the next.
- b) The collaborators icon allows you to add others to view, edit, manage, and/or submit the form.
- c) You may also add notes to communicate with other collaborators or create notes for yourself.
- d) Click 'Next' to move to the next page of the form. If you wish to save and return to the form later, click 'Save for Later.'



## **Continuing Review Application Data Entry:**

4. The next page will take you to the continuing review information page, where you will attach any applicable/supporting documents for continuing review. In this page, you will provide the dates of the current AHC site protocol application, sponsor protocol, and any investigator brochures or drug inserts.

Adventist HealthCare	a Collaborators	Continuing Review Information	*	Page 2 of 7
a Review Continuina Review Informatio	on			
, ,	Continuing Review Instructions			Add Note
	Office at (301) 315-3400 with any quest	bility to ensure that continuing approval is obtained prior ions. Submit this application with associated documental / be conducted after the expiration date and no extensio	ion at least 45 da	ays before the IRB approval
	Please attach any applicable/supportin	g study documents for continuing review. (Required)		Add Note View Audit
	[Add Attachment]	form(s) Current Trivest Adl data and sa revision the IRB Grant proposal submitted Related FDAC Monitoring rep review Current Delega	te Protocol Appliu rr Protocol RB approved con igator's Brochure, Cumulative Tablé (ety monitoring re al/Interim Report if new or revised mmunications sin es of any publicat vrts/audit findings	sent/assent/authorization , drug inserts approxits since the last continuing if not previously submitted to application not previously ce the last continuing review insince this fact ordinuing
	Please provide the version date of the Application. (Required)			
	Provide the version date of the current			
	Provide the version date of the current drug inserts and/or Instructions for Us			
	Previous Next Save for Later More •			

**Please note:** Questions on the x-forms are specifically conditioned based on your responses. In other words, certain questions will appear based on your answer(s) to a previous question(s). Furthermore, questions marked as required <u>cannot</u> be left unanswered. You will not be allowed to submit the form until you answer the required questions.

5. Indicate the current study status of the research study.

Adventist HealthCare	de Collaborators	Human Subjects Research		Page 3 of 7	Next
	Indicate the current status of the rese	arch study: (Required)		Add Note View Audit	
	<ul> <li>Study is actively enrolling/access to dat</li> <li>No subjects have been enrolled since the Study permanently closed to enrollmen active only for long-term follow-up of subj</li> <li>Study remains active only for data anal</li> <li>Other.</li> </ul>	ne last continuing IRB review/approval. t of new subjects, all subjects have completed all research-re jects.	elated interventions; and	research remains	
	Previous Next Save for Later More	•			

6. If the study is actively enrolling, you must provide more information on newly enrolled and consented subjects consented as well as any subject attrition.

Adventist HealthCare	af Collaborators	Enrollment Numbers and Demographics	<ul> <li>Page 4 of 9</li> </ul>	Next
Continuing Review Enrollment Numbers and Dem	ographics			
	Have you enrolled new subjects since t	the last review? (Required)	Add Note View /	udit
	● Yes ○ No			
	Site Specific Enrollment Information		Add Note View /	udit
	Number of Subjects Consented & Enro	lled Since Last IRB Review (Required)		
	Total Number of Subjects Consented 8	Enrolled (Required)		
	Number of Subjects Consented Not En	rolled Since Last IRB Review (Required)		
	Total Number of Subjects Consented N	lot Enrolled (Required)		
	Were any subjects removed from the s Ves No	study or withdrew early at this site? (Required)		
	Number of Subjects who Completed A	I Research Activities Since Last Review (Required)		
	Total Number of Subjects who Comple	ted All Research Activities (Required)		

Previous Next Save for Later More •



7. After providing the enrollment information, you must provide the racial/ethnic background of **only newly consented and enrolled subjects since the last IRB review.** 

Adventist HealthCare	A Collaborators		Racial & E	thnic Categories	¥	Page 5 of	f 9	Next
ontinuing Review Racial & Ethnic Categories								
	Number of subject	s consented and enrolled	at the site since last I	RB review		Ad	dd Note	
	4							
	Racial & Ethnic Cat	egories Enrollment Infor	mation			Δι	dd Note	
		-		nsented and enrolled at this si	ite. Click 'save' after enteri			
						Add Note Vie	aw Audit	
				<u>sented and enrolled subj</u> n. Click ' <mark>save</mark> ' after enteri		ws in the table	e	
	(Required)							
	# of Subjects*	Gender*	Race*	1	Ethnicity*	A	ction	
	1	•		۲.		<ul> <li>Sa</li> </ul>	ave	
	Previous Next Sa	ve for Later More +						

- a) The number for subjects consented and enrolled at the site since the last IRB review is available for your convenience.
- b) Enter the subject's ID, gender, race, and ethnicity. If there were no subjects consented and enrolled since the last IRB review, enter '0' for the subject ID, and 'N/A' for the drop down.
- c) You must save the information entered before adding another row of information.
- 8. The next following pages will ask you about the protocol and consent process and safety and adverse events.

## **Reportable Event Information**

- 9. If you are reporting any reportable events to the IRB at continuing review, you need to submit the reportable event form. Based on your response(s) to the questions on the safety and adverse events page, the reportable event form will populate towards the end of the continuing review application. From there, you can attach any cumulative tables.
- 10. Please refer to the Reportable Event Resource Guide for Research Personnel and Principal Investigators for more guidance on how to fill out the form.

## **Amendment Information**

- 11. If you are submitting an amendment with the continuing review application, you need to complete the amendment request form. Based on your response(s) to the questions on the research personnel page, the amendment request form will populate towards the end of the continuing review application.
- 12. Please refer to the Amendment Request Form Resource Guide for Research Personnel and Principal Investigators for more guidance on how to fill out the form.

## **Risk/Benefit Ratio**

13. Lastly, you will be prompted to assess the risk/benefit ration prior to submission.



## PI Sign-Off and Admin Pre-Review:

- 14. After you have entered all the required information, you may now submit the form or save for later. Once the form is submitted, it will go directly to the PI for sign-off.
- 15. The PI will receive the following email, as shown below, which will include a link to the continuing review application.

IRB@adventisthealthcare.com mhalague@terpmail.umd.edu
Continuing Review for 2018-08 Requires Signature

9:57 AM

Dear Test PI, MD,

Maria Halaguena has submitted a continuing review form for 2018-08-CREST-H.

Click here to review and sign-off on the submission. Continuing Review

For additional questions, please contact the IRB Office at 301-315-3400.

16. If the PI has suggested comments/modifications to the continuing review application prior to IRB submission, you will receive the following email, as shown below. The continuing review application will go back to data entry and you may edit the form accordingly.

PI Request Changes to Continuir	ng Review for 2018-08	~
IRB@adventisthealthcare.com	mhalague@adventisthealthcare.com	Tue 10:59 AM

#### Dear Maria Halaguena,

Test PI, MD has reviewed the continuing review for 2018-08-CREST-H and is requesting changes before it can be submitted to the IRB.

PI requested changes:

Submit revised investigator brochure along with summary of changes..

Click here to access the form and make the changes. Continuing Review

For additional questions, please contact the IRB Office at 301-315-3400.

17. After you have finished making the revisions, the form will go back to the PI for sign off.

**Please note:** Every time a change is made to the study documents, the PI must sign off afterwards.

18. The IRB Office will review the continuing review application and if there are any changes requested, you will receive the following email.



IRB@adventisthealthcare.com mhalague@terpmail.umd.edu; mhalague@adventisthealthcare.com -	Tue 11:18 AM
IRB Admin Requesting Changes to Continuing Review for Study 2018-08	~
IRB Study Number: 2018-08	
Study Title: CREST-H	
Dear Test PI, MD,	
The IRB office has administratively reviewed the above referenced submission for consistency and completeness.	
Please address the following questions:	
Submit word copy of the informed consent form.	
Click here to access the form. Continuing Review	

Your form is open for edits. Please respond to these concerns and include any revised documentation in the form. The IRB Office can be contacted at IRB@adventisthealthcare.com or 301-315-3400 with any questions.

Thank you.

19. To make the changes requested by the IRB Office, click on the blue form link and you will be directed to the x-form. The IRB Office will utilize the notes feature to communicate the required changes to the research study teams, which will make it easier to identify the required changes on the x-form. You may also use the notes feature to communicate with your collaborators by designating them as internal.

Add Note View       It is the Principal Investigator's responsibility to ensure that continuing approval is obtained prior to the expiration date. Please contact the objective that is application with any questicated determination at least 45 days before the IRB approval expiration date. No research activity may be conducted after the expiration date and no extensions can be granted.         Please attach any applicable/supporting study documents for continuing review. (recurred)       Add Note View         Mathement       Interest: 30/05/19 By: Maria Halguena Internat: No         Add Attachment       Delegation of Authority Log         Investigator brochure revised       Delegation Report/Audit         Infinitions reports       Delegation Report/Audit         Infinitions reports       Bonitoring Report/Audit         Infinitions reports       Sponsor Protocol         Sponsor protocol       Sponsor Protocol         Please approvide the version date of the current AHC Site Protocol       Authority Form         Please approvide the version date of the current AHC Site Protocol       Montoring reports and application not previous and the sound copy.         Current Delegation of Authority Form       Provide the version date of the current AHC Site Protocol						
Continuing Review Instructions       Add         It is the Principal Investigator's responsibility to ensure that continuing approval is obtained prior to the expiration date. Please constact the other expiration date. No research activity may be conducted after the expiration date and no extensions can be granted.         Please attach any applicable/supporting study documents for continuing review. (Required)       Add Note View         Mettered::30/05/19 By: Haria Halaguena. Internat: No       Implication date. No research activity may be conducted after the expiration date.         Add Attachment       Delegation of Authority Log       Investigator's Brochure         Investigator brochure revised       Delegation of Authority Log       Investigator's Brochure         Investigator brochure revised       Delegation of Authority Log       Monitoring Report/Loadit         Investigator brochure revised       Delegation of Authority Log       Investigator's Brochure         Investigator brochure revised       Delegation of Authority Log       Other reports         Infinitions reports       Bronicoling Report/Loadit       - Current Sponsor Protocol         Sponsor protocol       Sponsor Protocol       - Adverse Event Current Report for orevisual systematic         View resignator brochure revised       Browide the version date of the current AHC Site Protocol       - Adverse Event Current Protocol         Sponsor protocol       Sponsor protocol       - Related adsety monitoring revisual submi	Adventist HealthCare	de Collaborators	Continuing Review	w Information 🔹		Page 2 of 7
It is the Principal Investigator's responsibility to ansure that continuing approval is obtained prior to the expiration date. Please contact the Differ at (201) 315-940 with any questions. Sound this application that associated documentation at least 45 days before the JRB approveree in the application date. Neases contact the expiration date and no extensions can be granted.  Please attach any applicable/supporting study documents for continuing review. (Recurred) Add Note Verify and No	- Continuing Review Informat	on				
Office at (201) 315-3400 with any questions. Submit this application with associated documentation at least 45 days before the IRB approveres expiration date. No research activity may be conducted after the expiration date and no extensions can be grated. Please attach any applicable/supporting study documents for continuing review. (Required) Add Note Vie Entered: 20/05/19 By: Haria Nalaguena Internat. No Submit informed consent form with IRB stamp and word copy. Add Attachment And Attachment Add Attachment And Attachment revision And Attach		Continuing Review Instructions				Add Note
Entered: 02/05/19       By: Maria Kalaguena Internal: No         Submit informed consent form with IRB stamp and word copy.         Add Attachment         > DOA         Y Info for Use         > Info for Use         > Instructions for Use         > Monitoring Report/Audit         > Sponsor protocol         > Sponsor protocol         Provide the version date of the current AHC Site Protocol         Adverse provide the version date of the current AHC Site Protocol         By/Sro19         Provide the version date of the current Investigator's Brochure.         By/Sro19         Provide the version date of the current AHC Site Protocol.         By/Sro19         Provide the version date of the current Investigator's Brochure.         By/Sro19         Provide the version date of the current Investigator's Brochure.         By/Sro19         Provide the version date of the current Investigator's Brochure.         By/Sro19         Provide the version date of the current Investigator's Brochure.         By/Sro19		Office at (301) 315-3400 with any qu	estions. Submit this application with	h associated documentation at lea	ast 45 days before the	
Submit informed consent form with IRB stamp and word copy.         Add Attachment         Add Attachment         Yer for fully		Please attach any applicable/suppo	rting study documents for continu	ing review. (Required)	Ade	d Note View Audit
Add Attachment       Required study documents include:         Add Attachment       Delegation of Authority Log Instructions for Use Investigator Stochure revised Changes       Delegation of Authority Log Investigator's Brochure Changes       Delegation of Authority Log Investigator's Brochure Monitoring Report/Audit Findings       Delegation of Authority Log Investigator's Annual Interim Report In do previously submitter Delegation of Authority Facility Provide the version date of the current AHC Site Protocol Monitoring reports/audit findings since the last continuing rev Delegation of Authority Form         Provide the version date of the current AHC Site Protocol Monitoring Provide the version date of the current AHC Site Protocol Monitoring reports/audit findings since the last continuing review       Current Delegation of Authority Form         Provide the version date of the current AHC Site Protocol Monitoring Provide the version date of the current Investigator's Brochure,       Current Delegation of Authority Form		Entered: 03/05/19 By	/: Maria Halaguena Internal: No		<i>G</i> 0	× .
Wedd Auduitients       Delegation of Authority Log         Y Droke Use       Information of Use         Y Information reports       Monitoring Report/Audit         Y Honkor reports       Monitoring Report/Audit         Y Sponsor protocol       Sponsor protocol         Provide the version date of the current AHC Site Protocol.       System         System       Provide the version date of the current Investigator's Brochure.		Submit informed consen	t form with IRB stamp and word copy			
Instruction for Use     Investigator Produce     Investigator Prod		Add Attachment		Required study documents includ	le:	
Application. (required) 3/5/2019 Provide the version date of the current Sponsor Protocol. 3/5/2019 Provide the version date of the current Investigator's Brochure,		<ul> <li>Info for Use</li> <li>Investigator brochure revised</li> <li>Investigator brochure summary of changes</li> <li>Monitor reports</li> </ul>	Instructions for Use Investigator's Brochure Investigator's Brochure Monitoring Report/Audit Findings	Current Sponsor Protoc Most recently IRB apro- form(s)     Current Investigator's I Aid varse Event Cumulat Aid varse Event Cumulat Aid varse And safety mon review Sonsor's Annual/Interni Copy Sal, If new c submittee Related FDA communicat Nontoring reports/audit review	col ' roved consent/assent/, roved consent/assent/, Brochure, drug inserts tive Table intoring reports since the im Report if not previo or revised application r publications on this to the flast cos y publications on this to the flast cos the flast	e last continuing usly submitted to not previously intinuing review opic or related to
Provide the version date of the current Investigator's Brochure,		Application. (Required) 3/5/2019 Provide the version date of the curr				
Provide the version date of the current Investigator's Brochure,						
drug inserts and/or Instructions for Use. 3/5/2019		drug inserts and/or Instructions fo	rent Investigator's Brochure, r Use.			

**Please note:** You cannot submit the form until the changes requested by the IRB Office have been made.

20. After you have made the changes requested by the IRB Office, the form will go to the PI for sign off.

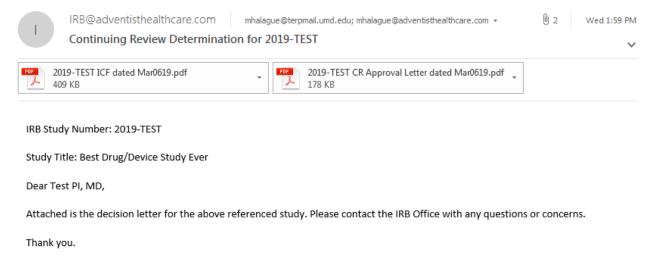


21. If no additional changes are requested by the PI and IRB Office, the continuing review is ready to be reviewed by the IRB.

#### **IRB Review:**

#### **Expedited Review**

22. If the continuing review application is reviewed via expedited review and receives a fullapproval, the study team should receive an outcome letter within 4-5 business days. The determination letter and informed consent form (if applicable) will be sent to the PI and creating user via email, as shown below.



23. If the continuing review application receives a determination other than a full-approval, you will receive an email, as shown below, prompting you to make revisions to your application. To make the changes, click on the blue form link. After you have made revisions, the form will go to the PI for sign-off and the IRB will conduct a second review.



IRB@adventisthealthcare.com	mhalague@adventisthealthcare.com	Wed 4:17 PM
Study T2019-007 Continuing Review Requires Changes		~

IRB Study Number: T2019-007

Study Title: INITIAL REVIEW APPLICATION # 4

Dear Test PI, MD,

The IRB has reviewed the continuing review documents for the above referenced study via expedited review and determined that modifications are needed. Please address the following questions:

test

Please click the form link to access the form and make changes. Continuing Review Application

Thank you.

#### **Referral to Full-Board**

24. If the continuing review is deferred to full-board review, you will receive the email, as shown below, informing you of the referral.

-	IRB@adventisthealthcare.com	mhalague@terpmail.umd.edu; mhalague@adventisthealthcare.com 👻	7:41 PM
5	Study 2018-07 Referred to Full-Board		

IRB Study Number: 2018-07

Study Name: EnSite Precision Observational Study

Dear Test PI, MD,

2018-07-EnSite Precision Observational Study was referred for full-board review. Please contact the IRB Office at IRB@adventisthealthcare.com or 301-315-3400 with any questions.

Thank you.

#### **Full-Board**

25. After the convened IRB meeting, the PI and creating user will receive an email containing the determination letter and informed consent form (if applicable) within two days of the IRB meeting.



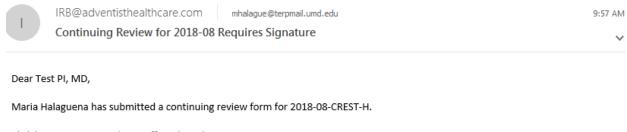
26. If the IRB has determined that modifications are needed to the continuing review, the IRB Office will send an email to the PI and creating user containing the changes requested, as shown below. The form will then go back to data entry and PI sign off.

🕰 Reply 🕼 Reply All 🕰 Forward					
IRB@adventisthealthcare.com mhalague@terpmail.umd.edu; Maria Halaguena +	0 2 9:24 AM				
Study T2019-004: Continuing Review Conditional Approval					
🕦 If there are problems with how this message is displayed, click here to view it in a web browser.	~				
T2019-004 CR Conditional Approval Letter dated MarI319.docx 48 KB					
CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.					
IRB Study Number: T2019-004					
Study Title: Strategies Healthcare Managers Use to Reduce Hospital Acquired Infections					
Dear Test PI, MD,					
Attached is the continuing review conditional approval letter for the above referenced study. Please respond to the IRB's concerns within the letter (attached in Microsoft Word for your convenience) and include any revised documentation.					
Please contact the IRB office at IRB@adventisthealthcare.com or (301) 315-3400 with any questions.					
Thank you.					

27. To view the determination letter and stamped informed consent form within IRBManager, go to the study profile and click on the 'amendment event'. On the 'actions side bar', go to 'attachments' and then 'generated docs'.

#### **Principal Investigator Guidance:**

1. You will receive an email from <u>IRB@adventisthealthcare.com</u> informing you an x-form has been completed by a research staff member. The email will include a link to the continuing review application.



Click here to review and sign-off on the submission. Continuing Review

For additional questions, please contact the IRB Office at 301-315-3400.

- 2. The blue form link will take you directly to the x-form for your signature. You can see the information entered by the creating user.
- 3. If you agree with the submission information entered, you will electronically sign-off on the document by inputting your IRBManager password.



Adventist HealthCare	Collaborators	PI Attestation and Signature	×	Page 1 of 1	Next
Continuing Review PI Attestation and Sign	ature				
	Is this continuing review ready to be sen	t to the IRB? (Required)		View Audit	
	© Yes ◯ No				
	PI Attestation			View Audit	
By entering your password in the space below, you acknowledge this continuing review submission and are electronically signing this form. (Required) To sign, enter password for mhalague@terpmail.umd.edu					
	Previous Next Save for Later More				

4. If you would like to request changes to the submission, you can indicate the changes you are requesting in the text box. These comments will go directly to the creating user.

Adventist HealthCare	a Collaborators	PI Attestation and Signature	T	Page 1 of 1	Next
Continuing Review PI Attestation and Sign	ature				
	Is this continuing review ready to be sent	to the IRB? (Required)		View Audit	
	⊖ Yes ● No				
	Indicate the changes you are requesting.	(Required)		View Audit	
	Submit revised investigator brochure along wi	th summary of changes.		e comments will go directly to the submitter.	
Previous) Next Save for Later More •					

5. Please be aware that your signature is required every time a change is made to the study documents. Any changes made to the study documents will be highlighted in yellow.



# Terminology for IRBManager:

- <sup>1</sup>X-forms: online version of the currently existing submission documents with slight modifications
- <sup>2</sup>Projects: research studies.
- <sup>3</sup>Study Events/Events: actions or reviews for research studies. Examples include amendments, continuing review, and reportable event
- <sup>4</sup>Protocol site output: where the study will primarily take place. There may be more than one site listed.
- <sup>5</sup>Agent type: description of the nature of the study or the investigational aspect of the study (e.g., observational, specimen review, drug, device, etc.)
- <sup>6</sup>Creating user: the study staff member who started the x-form data entry .