

Responding to Contingent Approvals in IRBManager

FIRST GO TO: <https://login.irbmanager.com>

Log on to IRBManager
 You will see the screen below
 Click on the blue protocol code

Actions	Protocol Code	Site	Investigator	Description	Status
Show Sponsor Protocol Codes	04-014-CCMC	CCMC Main Building		Calcium Kinetics in Children with Crohn's Disease	Active
	05-040-CCMC	CCMC Main Building		Does Crohns Disease Affect the Number and Function of Circulating Osteoblasts?	Continued
Recent Items				A Phase 3, Randomized, Open-label, Parallel-group, Multicenter Trial to Evaluate the Safety and Efficacy of Infliximab (REMICADE) in Pediatric Subjects with	
	04-014-CCMC				

On the next screen, scroll to the bottom and look for the Events

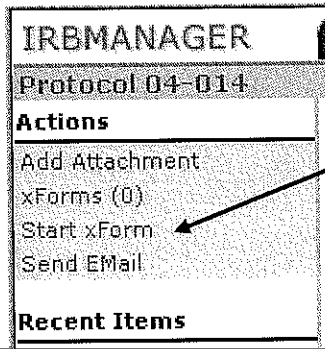
Click on the blue link "revisions requested"

Action	Name	Primary	Role
	Lincoln, Miriam R.N.	<input checked="" type="checkbox"/>	Coordinator
	Sayed, Wael MD		Co-Investigator
	Sylvester, Francisco MD	<input checked="" type="checkbox"/>	Co-Investigator
	Zeiter, Donna M.D.		Co-Investigator

Action	Name	Type	Date	By
	01-080 stamped substudy consent 12.8.09.pdf	Informed Consent	Dec-10-2009	kneild
	01-080 stamped main consent 12.8.09.pdf	Informed Consent	Dec-10-2009	kneild
	01-080 signed continuing approval letter 12.8.09.pdf	Generated Document	Dec-10-2009	kneild

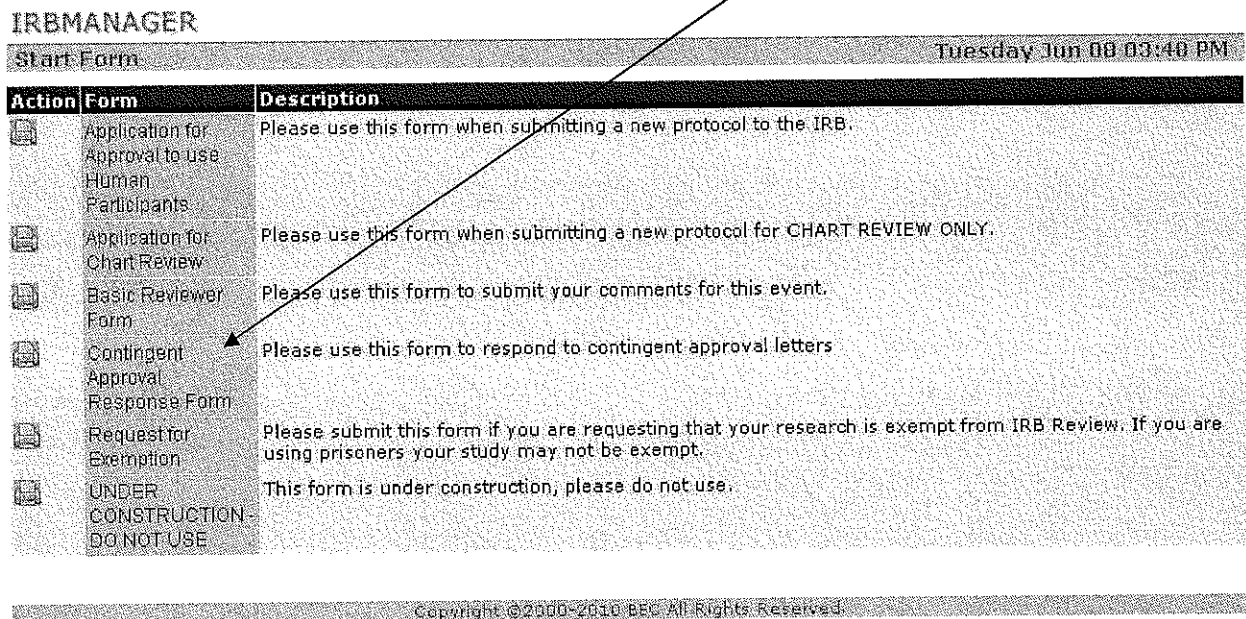
Action	Event	Instance	Start	Complete	Primary Reviewer	Secondary Reviewer	Last Reviewed by IRB
	Revisions Requested	(0)	11/20/2009	12/07/2009	Not Displayed	Not Displayed	12/14/2009
	Continuing Review	(5) (1)	11/10/2009	12/07/2009	Not Displayed	Not Displayed	12/14/2009

- On the Action List [upper left side of screen] click on "Start xForm"



IRBMANAGER
Protocol 04-014
Actions
Add Attachment
xForms (0)
Start xForm
Send EMail
Recent Items

From the menu, choose "Contingent Approval Response Form"



IRBMANAGER
Start Form Tuesday Jun 08 03:40 PM

Action	Form	Description
	Application for Approval to use Human Participants	Please use this form when submitting a new protocol to the IRB.
	Application for Chart Review	Please use this form when submitting a new protocol for CHART REVIEW ONLY.
	Basic Reviewer Form	Please use this form to submit your comments for this event.
	Contingent Approval Response Form	Please use this form to respond to contingent approval letters
	Request for Exemption	Please submit this form if you are requesting that your research is exempt from IRB Review. If you are using prisoners your study may not be exempt.
	UNDER CONSTRUCTION - DO NOT USE	This form is under construction, please do not use.

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Once the form has been completed it is also necessary to make the changes in the "notes" section of the original protocol application: Please see next page.

Responding to contingent approvals

Go to the "new protocol" – Click on the "hand" icon

Initial Approval Date	Comments	Additional Site Date				
▼ Contacts for this Protocol-Site						
Action	Name	Primary	Role			
X	Gasuk, Jocelyn		Coordinator			
X	Lapidus, Garry PA-C, MPH	<input checked="" type="checkbox"/>	Co-Investigator			
	Salameen, Hassan MBBS, MPH	<input checked="" type="checkbox"/>	Coordinator			
▼ Other Sites						
There are no other sites for this Protocol.						
▼ Attachments						
There are no attachments for this site.						
▼ Events						
Action	Event	Instance	Start	Complete	Primary Reviewer	Last Secondary Reviewed by IRB
X	Revisions Requested	(0)	Revise application; complete request for waiver; submit COI forms; CITI training	06/30/2010	Freeman, Jeanne JD, MA	08/09/2010
X	New Protocol	(3) (1)		06/23/2010	Freeman, Jeanne JD, MA	07/12/2010
▶ Notes (1)						
▶ Generated Documents (0)						

Then click on xForms (1) on the left hand "Action bar"


IRBMANAGER **HOME** **CREATE A STUDY** **REPORTS &**

Protocol Event Details

<p>Actions</p> <ul style="list-style-type: none"> Edit Event Sub Screen Attachments (3) Add Event Note View Event Step Audit Generate Doc xForms (1) Start xForm Abandon Steps Send EMail Add Follow Up Event Done <p>Recent Items</p>	<p>Protocol-Site</p> <p>Protocol 10-065 - CCMC Investigator Campbell, Brendan MD, MP</p> <p>Event</p> <p>Event Name: New Protocol</p> <p>Event Instance: <input type="text"/></p> <p>Primary Reviewer: <input type="text" value="Jeanne Freeman (Alt)"/></p> <p>Originating Event:</p> <p>Contingent Approval Date: <input type="text" value="June 29, 2010"/></p> <p>Notes</p> <p>Action Note</p>
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Click on the application — this will open the application

Action	Form	Identifier	Stage	Status
	Application for Chart Review (old version)	Screening, Brief Intervention and Referral to Treatment	Load Into IRB Manager	Complete

Go to the section that you would like to add a note to
Then click on "add note"

Waiver of Informed Consent	Add Note View Audit
Item selected: Yes	<i>Please check yes if you are requesting a waiver of consent/authorization for the use of retrospectively collected data (data already exists in the record at the time this protocol is submitted) and complete the questions below) and wish to waive the requirements for informed consent and HIPAA authorization.</i>
Consent Already Obtained	Add Note View Audit
Item selected: No	<i>Please check here if informed consent was already obtained which permits the current research.</i>
Subject's Understanding of How Samples Would be Used	Add Note View Audit
No answer entered.	<i>What was the subject's understanding of how the samples would be used?</i>
Copy of Consent	Add Note View Audit
No attachments.	<i>Please attach a copy of the consent form, if available.</i>

THE CONTINGENT RESPONSE FORM IS A VERY SHORT [ONE PAGE] FORM WHERE YOU CAN RESPOND TO THE CONTINGENT APPROVAL LETTER AND ATTACH ANY DOCUMENTS THAT MAY BE NECESSARY.