

Notifications Encyclopedia

Study Manager



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Your IREx user account has been created

Recipients

Reviewing IRB, Relying HRPP, Study Managers, Site Study Teams

Category
User Account

Occurrence

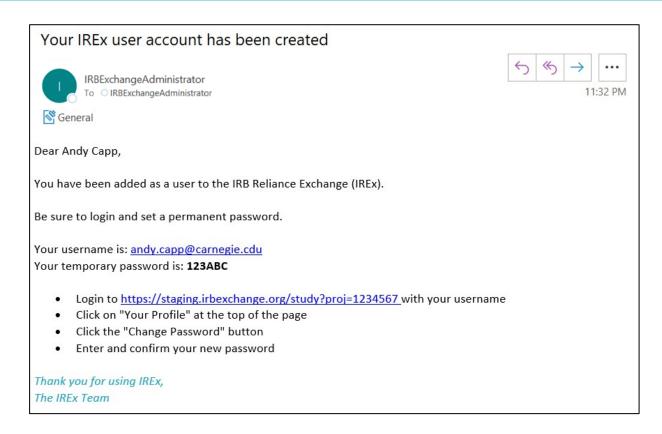
When someone first gains access to IREx

Attachments

None

Why

To receive login information for IREx



IREx Password Reset Request

Recipients

Reviewing IRB, Relying HRPP, Study Managers, Site Study Teams

Occurrence

When someone forgets their password

Why

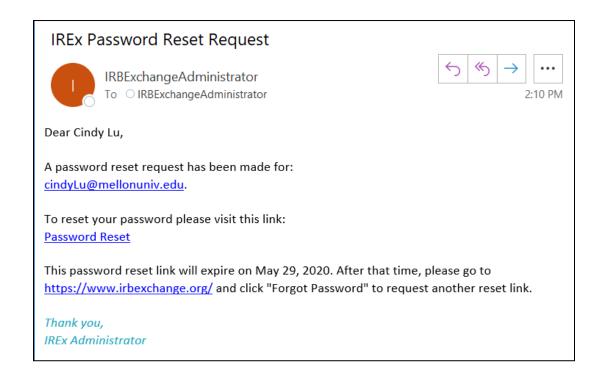
To receive temporary password to log into IREx

Category

User Account

Attachments

None



Your study is in IREx

Recipients

Study Managers

Occurrence

When the Study Manager is added to a study In IREx

Why

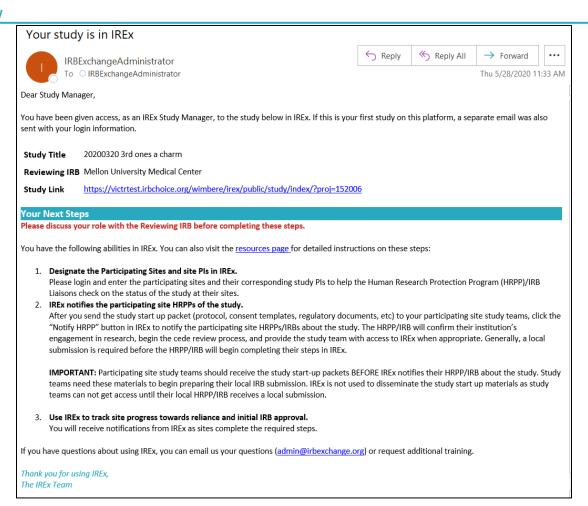
To alert the Study Manager and provides next steps

Category

Study Access

Attachments

Link to Resources page



IREx Study at your site

Recipients

Study Managers, Relying HRPP, Site Study Teams

Occurrence

When the Study Manager presses the Notify HRPP button to alert the site HRPP and study team that the study is in IREx.

Why

To connect the local HRPP & study team so they can discuss how to initiate reliance at their site.

Category

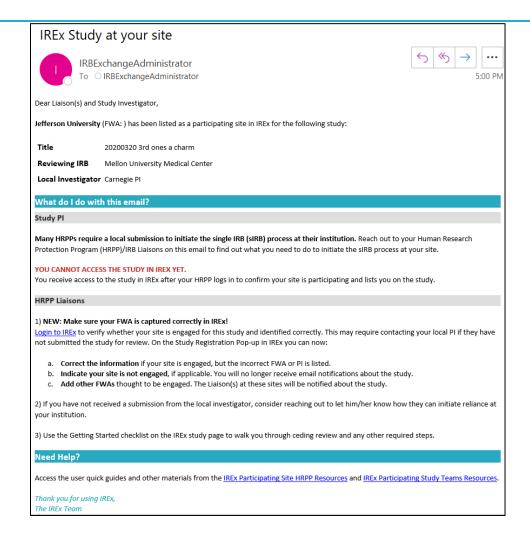
Site Engagement

Attachments

None

Note

Links to IREx study page, Participating Site HRPP resource page, & Participating Study Team resource page



IREx: New Site Registered for Study

Recipients

Reviewing IRB, Study Managers

Occurrence

When the Relying HRPP confirms their FWA and PI are engaged for a study

Why

To alert the Reviewing IRB & Study Manager that a site has registered

Category

Site Engagement

Attachments

None

Note

This email may identify an additional FWA engaged (Combo Site), FWA changed, PI changed

Preview

IREx: New Site Registered for Study





4:37 PM

Dear Study Manager and Reviewing IRB Liaison, An HRPP Liaison completed registration for the study as shown below:

Study Title	20200320 3rd ones a charm		
Site	Eastman Medical Center of Ohio (#45648974865)		
PI	Only PI (onlypi@eastman.cdu)		
PI Access	Only PI now has access to the study.		

If you have questions about this site's registration, please contact Alys Kim.

STUDY LINK: Click here to view the study

Thank you,

IREx Administrator

[WARNING: This email came from an external source. Please treat this message with additional caution.]

IREx: Site Declined Engagement for Study

Recipients

Reviewing IRB, Study Managers

Occurrence

When the Relying HRPP declines that their FWA is engaged for a study

Why

To alert the Reviewing IRB & Study Manager that a site has declined registration

Category

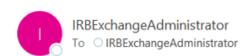
Site Engagement

Attachments

None

Preview

FW: Mars -- IREx: Site Declined Engagement for Study



4:37 PM

Dear Study Manager and Reviewing IRB Liaison,

An HRPP Liaison indicated their site is not engaged for the study as shown below:

Study Title	Drive-Thru Influenza Vaccinations in Mars			
Site	Carnegie University Medical Center (#12345678)			
PI	Carnegie PI (pi@carnegieu.cdu)			
The Liaison updated the site/PI information as shown below				
Site is not engaged	Carnegie University Medical Center (#12345678) provided the following reason they are not engaged:			
	This site will not sign the required agreements.			
	This information is captured on the Status Summary under "Non-Engaged Sites".			

If you have questions about this site's registration, please contact 'Asri Mumpuni.

STUDY LINK: https://test.irbexchange.org/main-branch/public/study?proj=898219

Thank you, IREx Administrator

IREx: Notification of Reliance

Recipients

Reviewing IRB, Relying HRPP, Study Managers, Site Study Team

Occurrence

When the Relying HRPP accepts the SSRP to Indicate Reliance on the Reviewing IRB

Why

To confirm the Relying HRPP has Indicated Reliance

Category

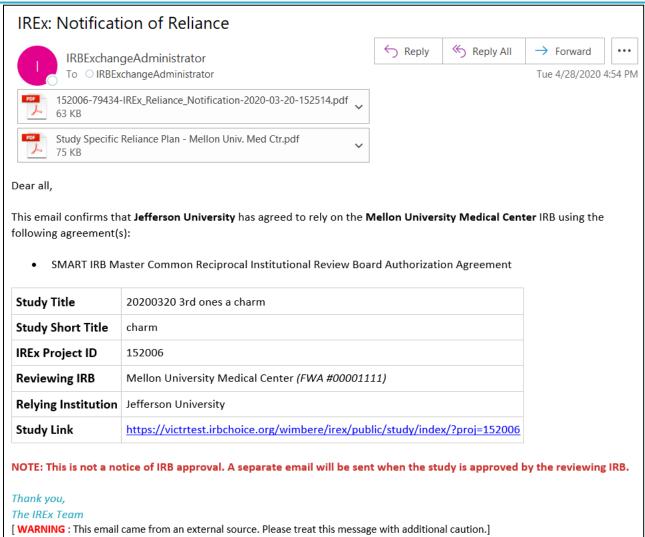
Reliance Decision

Attachments

SSRP, Reliance Notification

Note

This is not a notice of IRB approval.



IREx Update: New Local Considerations Complete

Recipients

Reviewing IRB, Study Manager

Occurrence

When the Local Considerations have been completed

Why

To alert the study manager so they can prescreen the information and export it for submission to the Reviewing IRB

Category

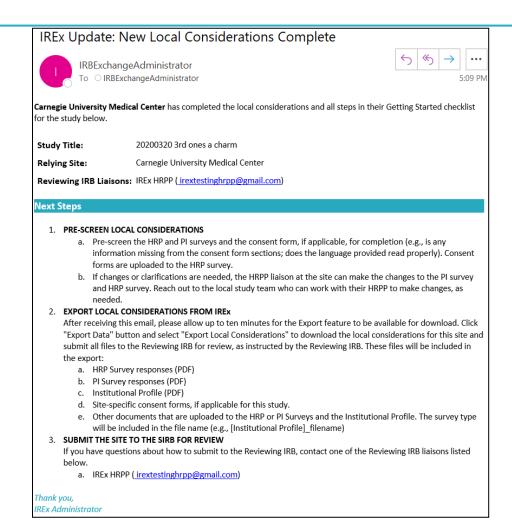
Local Considerations

Attachments

Link to Reviewing HRPP email

Note

May includes Notes in RED if Relying sites tasks are incomplete (i.e., indicating reliance, agreements)



IREx: Site Updated Local Considerations Response

Recipients

Reviewing IRB, Study Manager

Occurrence

When the Relying HRPP has changed the Local Considerations responses to the PI and/or HRP Survey

Why

To alert the study manager and sIRB that a Local Considerations survey was changed by the Site

Category

Local Considerations

Attachments

None

Preview

IREx: Site Updated Local Considerations Response



Can be for the PI or HRP Survey

Dear Coordinating Center / Lead Study Team,

University of Kentucky has modified their responses to the Local PI Survey on the following study:

20200414 Asri Combo Carnegie sirb

Survey response changes are noted below.

Survey Field	Previous Response	Updated Response
Site Investigator's Phone	555-555-5555	555-555-6666
Please review the planned list of personnel who will be engaged in human subjects research and indicate whether COI applies:	I have verified there are no financial interests to disclose	I have verified any relevant interests have been disclosed per my institutional policy and managed, as applicable
RECRUITMENT PLAN: Are there any differences to the initial contact and/or recruitment plan at your site from that described in the protocol or associated documents based on local requirements or state law?	No	Yes

If this information has already been submitted to the Reviewing IRB for review, please be sure to communicate these changes to the Reviewing IRB for this site.

Note: the completed surveys are now viewable on the Status Summary tab in IREx; however, please allow up to ten minutes for the Export feature to be available for download.

Click here to view the study.

Thank you,

IREx Administrator

IREx: Reviewing IRB uploaded new approval for Lead Site

Recipients

Study Managers

Occurrence

When the Reviewing IRB uploads an approval for the Lead Site

Why

To notify the Study Manager that Relying Site Approvals can be uploaded

Category

Approval

Attachments

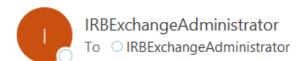
None

Note

Email can be for initial approval, continuing reviews, or amendments

Preview

IREx: Reviewing IRB uploaded new approval for Lead Site





2:30 PM

Mellon University Medical Center has uploaded a new approval for the Lead Site in IREx

for the study below:

TITLE: 20200320 3rd ones a charm

TYPE OF APPROVAL: Initial Study: Expedited

LINK: Click here to view the study

Type of Approval:
Initial Study: Full
Initial Study: Expedited
Continuing Review: Full
Continuing Review: Expedited
Amendment: Full
Amendment: Expedited

Now, approvals can be uploaded for any relying sites with approval.

Thank you for using IREx, The IREx Team

IREx: Reviewing IRB updated Lead Site approval

Recipients

Study Managers

Occurrence

Category Approval

Attachments

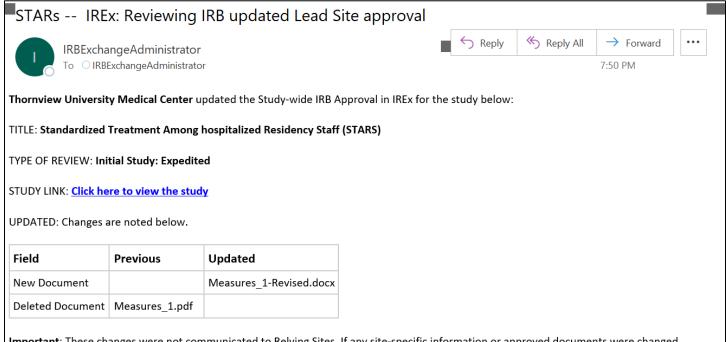
When the Reviewing IRB updates the Overall Study approval

None

Why

To notify the Study Manager that the sIRB has updated an existing approval in IREx. Relying sites are NOT notified of any changes, unless the determination letter is changed (see next notification)

Preview



Important: These changes were not communicated to Relying Sites. If any site-specific information or approved documents were changed, update relying sites' IRB approvals in IREx to notify them of the updated approval.

Thank you, The IREx Team

IREx: Reviewing IRB uploaded new approval for Lead Site

Recipients

Study Managers

Attachments

Approval Status

Category

Occurrence

When the Reviewing IRB or the Study Manager uploads a Continuing Review or Amendment approval for the Lead Site Attachments

None

Why

To confirm the approval was uploaded successfully and relying site approvals can now be uploaded.

Note

Note

Preview

IREx: Reviewing IRB uploaded new approval for Lead Site



IRBExchangeAdministrator
To OIRBExchangeAdministrator



12:25 PM

Mellon University Medical Center has uploaded a new approval for the Lead Site in IREx for the study below:

TITLE: 20200320 3rd ones a charm

TYPE OF APPROVAL: Continuing Review: Expedited

Type of Approval:
Continuing Review: Full
Continuing Review: Expedited
Amendment: Full
Amendment: Expedited

LINK: Click here to view the study

Now, approvals can be uploaded for any relying sites with approval.

Thank you for using IREx, The IREx Team

IREx: New IRB Approval For Your Site

Recipients

Reviewing IRB, Relying HRPP, Study Managers, Site Study Teams

Occurrence

When the Reviewing IRB approves a Site

Why

To alert the Relying HRPP, PI & coordinator that their site was approved by the Reviewing IRB and their documents can be downloaded

Category

Approval Status

Attachments

None

Preview

IREx: New IRB Approval For Your Site



5 ≪ → ···

Dear Liaisons and Study Contacts,

Mellon University Medical Center has shared IRB approval for your institution, Carnegie University Medical Center, in IREx for the study below:

Study Title: 20200320 3rd ones a charm

Type of Review /

Approval:

Initial Study: Expedited

Expiration Date: 3/9/2021

Study Link: https://victrtest.irbchoice.org/embryb/irex/public/study/index/?

proj=138554

Principal Investigators & Study Contacts:

Your approval documents are available in <u>IREx</u>. If you have any questions about your approval or future submissions, please contact the Coordinating Center (CC)/Lead Study Team (LST) or Reviewing IRB. If needed, contact information for the CC/LST is provided in a blue button just under the study title in IREx.

Thank you for using IREx,

The IREx Team

IREx: Updated Approval For Your Site

Recipients

Reviewing IRB, Relying HRPP, Study Managers, Site Study Teams

Occurrence

When the Reviewing IRB or Study Manager updates an existing approval for the site

Why

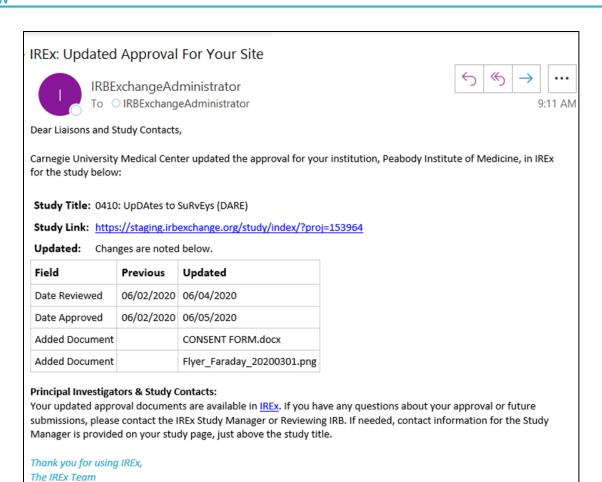
To alert the Liaisons and study team of any changed approval details, such as documents or dates

Category

Approval Status

Attachments

None



IREx: New IRB Approval For Your Site

Recipients

Reviewing IRB, Relying HRPP, Study Managers, Site Study Teams

Occurrence

When the Reviewing IRB or Study Manager uploads a Continuing Review approval for Sites

Why

To alert the Relying HRPP & PI of the Continuing Review approval and their new approval documents that are available

Category

Approval Status

Attachments

None

Preview

IREx: New IRB Approval For Your Site





Dear Liaisons and Study Contacts,

Mellon University Medical Center has shared IRB approval for your institution, Jefferson University, in IREx for the study below:

Study Title: 20200320 3rd ones a charm

Type of Review / Approval: Continuing Review: Expedited

Expiration Date: 4/28/2022

Study Link: https://www.irbexchange.org/study/index/?proj=19

Principal Investigators & Study Contacts:

Your approval documents are available in IREx. If you have any questions about your approval or future submissions, please contact the Coordinating Center (CC)/Lead Study Team (LST) or Reviewing IRB. If needed, contact information for the CC/LST is provided in a blue button just under the study title in IREx.

Thank you for using IREx, The IREx Team

IREx: New IRB Approval For Your Site

Recipients

Reviewing IRB, Relying HRPP, Study Managers, Site Study Teams

Occurrence

When the Reviewing IRB or Study Manager uploads an Amendment for the Participating Sites

Why

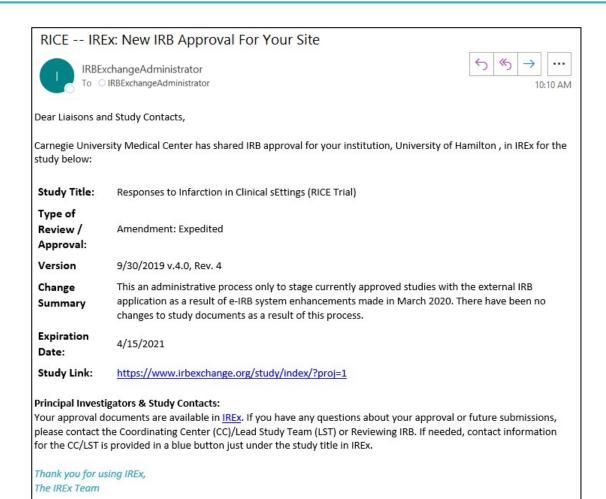
To alert the Relying HRPP & PI of the amendment – including a brief change summary – and their new approval documents that are available.

Category

Approval Status

Attachments

None



IREx: [Reviewing IRB updated Lead Site approval] or [Updated Approval For Your Site]

Recipients

Study Managers

Occurrence

When the Reviewing IRB updates the <u>Determination Letter</u> for a Continuing Review or Study-wide Amendment

Why

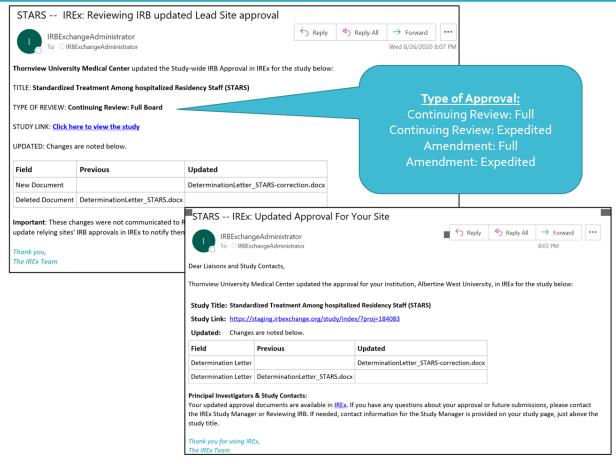
To notify the study manager and sites that the sIRB has updated the determination letter for their site. For CRs and SWAs, the Determination Letter for the Lead and Relying Sites are the same. Thus, when the Determination Letter is updated, it is automatically propagated to relying sites approved on that review.

Category

Approval Status

Attachments

None



Time to upload Continuing Review to IREx

Recipients

Reviewing IRB, Study Managers

Occurrence

When an existing study approval is 60, 30, 14, and 7 days from study expiration

Why

To remind the Reviewing HRPP that the study will expire so they can work with the Study Manager for Continuing Review

Category

Approval Status

Attachments

Link to the Reviewing IRB Resources page

