

COUHES Connect Restart Research



COUHES COVID-19 Update

On September 11, 2020, MIT allowed the restart of direct person-to-person human subject research, but restricted it to healthy adult subjects. We are now expanding the categories of subjects who may participate in direct person-to-person studies on campus to include subjects ages 12 and older and subjects with certain medical conditions who were previously excluded from campus research. The existing constraints on off-campus research will continue. Only healthy adults can participate in off-campus research. Please read the full <u>Guidance and Restart Process Instructions</u> for information on how to proceed.

For in-person research on campus, investigators are required to submit a Restart Research Request through COUHES Connect if they have not already submitted and received restart approval, or if there are changes to an already approved restart request (such as changes to location or subject interactions). Protocols with an approved restart request are otherwise NOT required to resubmit a new request.

Although all of your approved studies will appear in the Restart list, *only those with new direct person-to-person interactions planned* are required to submit a restart request.

To request the restart of your previously approved direct *person-to-person* human subjects research you must certify to the requirements.

If you are unable to meet ALL the certification requirements you will be prompted to attach an "Application to Restart Human Subjects Research" after you click "Save" or Submit."







COUHES Connect Restart Research Features

COUHES Connect is MIT's IRB platform where investigators can easily manage their human subject protocols.

All Investigators can electronically submit their Restart Research Protocol requests. Please note, only the protocol PI can submit the restart request.

Features of Restart Research:

- Hyperlink in Dashboard the Action tile for ease of navigation & awareness
- View Restart Status of all Active Protocols (Request to Restart, Request Submitted, Restarted, or Denied)
- Attestations for study locations that are On Campus, Off Campus, or Both On and Off Campus
- View all Pending Restart Requests (submitted but not yet approved)
- View Approved Restart Requests (click Restarted link)
- Export a list of your protocols
- Submit a Request to Restart (Submit action only available to the Study PI)
- Save your request to submit at another time (Save action available to other protocol personnel)
- Resubmit a denied request
- View current and previous Restart requests.





COUHES Restart Research Request Process & Requirements

Investigators will initiate a Restart Request through COUHES Connect for active Protocols and New Common Rule Exempt* Determined Evaluations listed in their Restart Research Request list tab.

*Old Common Rule exempt studies (approved prior to Jan. 21, 2019) will **not** appear on the Restart Research list. Please submit an Exempt Evaluation via COUHES Connect for a New Common Rule determination.

Restart Requests are required for any studies that include direct person-to-person human subject research.

Investigators complete the following:

- 1. The study PI must submit the Restart Request within COUHES Connect.
- 2. Based on your answers and potential risk, the system provides an automatic approval or requires you to attach an Application to Restart Human Subjects Research in order to submit: http://couhes.mit.edu/forms-templates.
- 3. A Restart Request that requires the Application to Restart Human Subjects Research are reviewed by COUHES on a rolling basis. Investigators must wait to receive an approval from COUHES before re-starting their studies.
- 4. Investigators are required to monitor the changes in COUHES policy: https://couhes.mit.edu/covid-19-updates.

Restart Requests MUST be submitted by the Principal Investigator on the study. For exempt research, the Faculty Sponsor and the Principal Investigator are responsible for reviewing the Restart Request and monitor changes posted on the COUHES website: http://couhes.mit.edu/.

Denied applications **CANNOT** commence with direct person-to-person research. Investigators are encouraged to update protocol in response to remote activities and resubmit a Restart Request later, as the situation evolves.





COUHES Connect Restart Research Process & Overview

- 1. Navigate to your Connect Restart Research Dashboard
- **2. Review** your list of active studies requiring restart requests
- **3. Request** to Restart a study
- **4. Select** if your study is On Campus, Off Campus, or Both On and Off Campus
- 5. Respond to the attestations (Yes/No questions) and Declarations (checkboxes) in the request window
- 6. Submit

IF:

- You respond positively (Y) to all the attestations
- You check the two declaration boxes

THEN: your study status automatically updates to restarted.

OR

IF:

- You respond negatively (N) to any of the attestations
- You check the two declaration boxes

THEN:

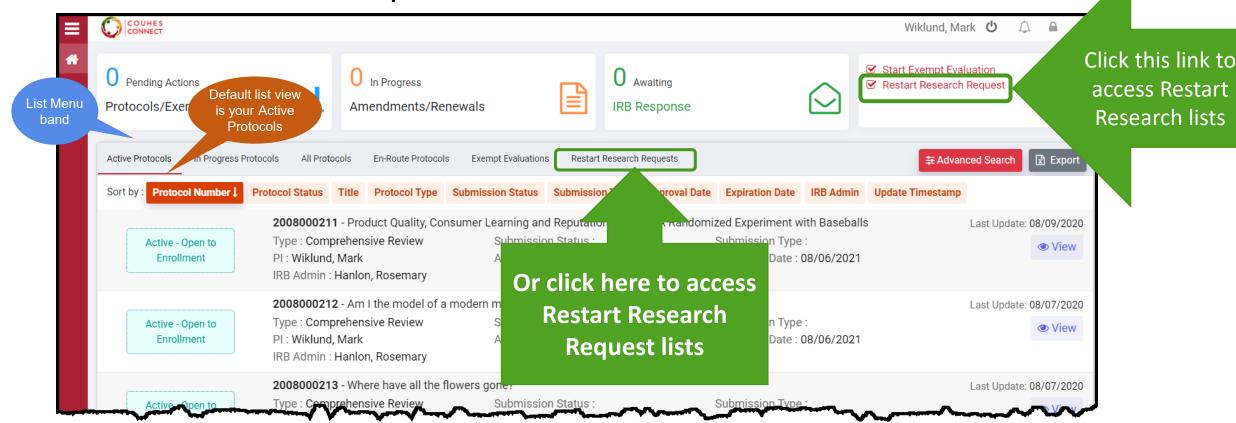
- Your request requires a completed application to Restart Human Subjects Research. The form is available for download from: http://couhes.mit.edu/forms-templates
- Upon Save, or Submit, The Request to Restart window updates with an upload file window for the application and a field for a note.
- Upon Submit, your request requires review and approval by COUHES before you can restart.



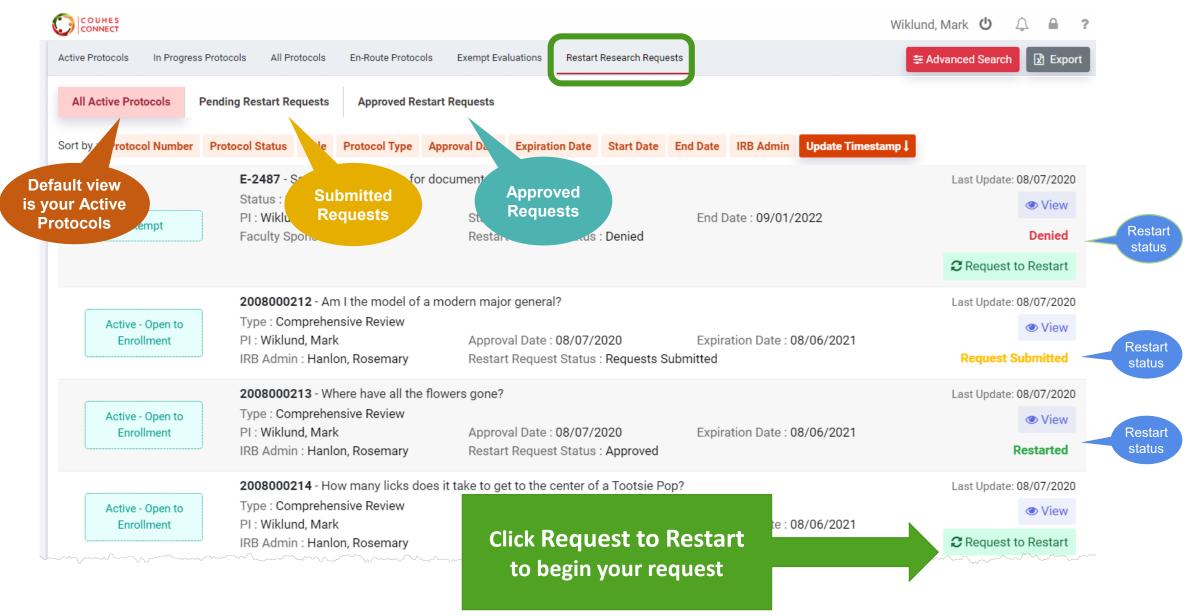


COUHES Connect Dashboard (authenticated through your MIT Kerberos ID and DUO/Certificate)

- 1. Launch COUHES Connect https://couhes-connect.mit.edu/connect/dashboard#/irb/dashboard
- 2. Your Connect Dashboard appears, populated with your protocols.
- 3. Click on Restart Research Requests in the list menu band to access the features.



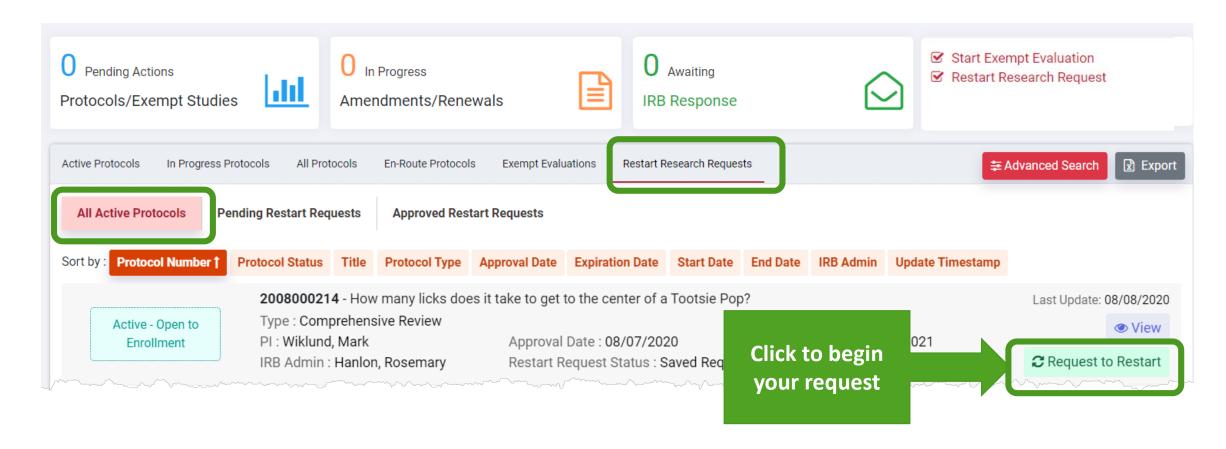
View Restart Status of all Active Protocols







Restart Research All Active Protocols







Request to Restart window

Active - Open to Enrollment 2009000222 - Do you belive in Magic?

Type : Comprehensive Review PI : Wiklund, Mark

IRB Admin : Hanlon, Rosemary

Approval Date : 09/14/2020 Restart Request Status : Expiration Date: 09/13/2021

Last Update: 02/17/2021

View

Request to Restart

Use **View** to open the *protocol*.

- 1. Click **Request to Restart** button on the subject protocol.
- 2. Select Study Location(s): On, Off, or Both On and Off Campus.
- 3. The window expands with the Attestation questions.
- 3. Select your responses to the attestation (Y/N) questions.
- 4. Check the boxes to respond to the declarations.

o you belive in Magic?			Active - Open to Enrollment
ype Comprehensive Review	PI Wiklund, Mark	Approval Date 09/14/2020	Expiration Date 09/13/2021
**		UST submit a Restart Request and certify to the tudy location or person-to-person interactions.	requirements below. Ongoing protocols with approved
Please note COUHES approval is nec and <u>now.mit.edu</u> .	essary but not sufficient for the resumptio	n of human subjects research. Additional MIT po	olicies may apply. See: <u>couhes.mit.edu/covid-19-updates</u>
including but not limited to subject r	ecruitment, experimental procedures, con:	sent mechanisms or study personnel), you will a	t of the study for which you do not already have approvi lso need to submit a separate Change Form to COUHES empt Evaluation then investigators must submit a new
although all of your approved studies	will show up in the Restart list, only those	with new direct person-to-person interactions p	planned are required to file a restart request.
f you are unable to meet ALL the cer	tification requirements you will be prompt	ed to attach an "Application to Restart Human Si	ubjects Research" after you click "Submit".
	ntend to restart person-to-person resear	ch activities. Study locations must aiready be in-	ciuded on your approved protocol.
Please select the location that you i On-Campus			





On Campus Attestation Questions

- Only subjects that are 12 years old or above will participate in on-campus research.
- All study personnel, subjects, and guests of subjects will comply with applicable national, state and local health authority requirements as well as MIT and DLC specific requirements regarding COVID-19 safety standards. This includes but is not limited to MIT Visitor Policy. See MIT Now for more information on the most up to date MIT Policy: now.mit.edu
- Confirm that you will maintain a registry of subjects and their guests for future tracking purposes that records their time and point of entry and exit.
- Prior to arrival at the study site, all subjects will complete an approved COVID-19 consent form addendum:
 <u>couhes.mit.edu/forms-templates</u>. This form must be completed by the subject and reviewed by the research study staff within 24 hours prior to the subject's arrival at the study site.
- Any subject who indicates they have tested positive for COVID-19 within the past 2 weeks, had contact with a COVID-19 positive patient within the past 2 weeks, currently has symptoms suggestive of COVID-19, or is at high risk for severe complications from COVID-19, will be excluded from the study.
- Confirm that you have reviewed the COUHES COVID-19 Updates and Restart Policies posted on the COUHES Website: couhes.mit.edu/covid-19-updates.





Off Campus Attestation Questions

- The study will only involve healthy adult subjects, and the inclusion criteria of your approved protocol does not involve the study of subjects who have any condition known to increase the risk of COVID-19:
 https://www.cdc.gov/coronavirus/2019-ncov/index.html
- I attest that vulnerable subjects will be EXCLUDED from the study (children, pregnant women, residents in a nursing home or a long-term care facility, or the cognitively impaired).
- All study personnel and all subjects will comply with applicable national, state and local health authority requirements regarding COVID-19 safety standards.
- Prior to arrival at the study site, all subjects will complete an approved COVID-19 consent form addendum:
 http://couhes.mit.edu/forms-templates. This form must be completed by the subject and reviewed by the research study staff within 24 hours prior to the subject's arrival at the study site.
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Both On and Off Campus Attestation Questions

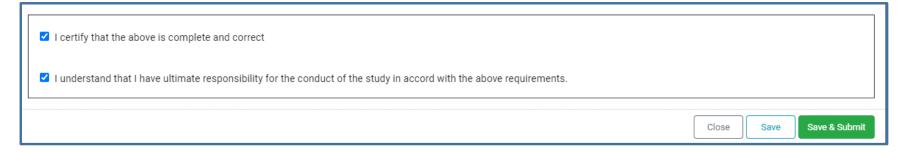
- For subjects that will be enrolled on campus, only subjects that are 12 years old or above will participate in the research.
- For subjects that will be enrolled on campus, confirm that you will maintain a registry of subjects and their guests for future tracking purposes that records their time and point of entry and exit.
- For subjects that will be enrolled off campus, only healthy adult subjects without any condition known to increase the risk of COVID-19 (https://www.cdc.gov/coronavirus/2019-ncov/index.html) will participate in the off-campus research.
- For subjects that will be enrolled off campus, I attest that vulnerable subjects will be EXCLUDED from the study (children, pregnant women, residents in a nursing home or a long-term care facility, or the cognitively impaired).
- For both on campus and off campus research, all study personnel, subjects, and guests of on-campus subjects will comply with
 applicable national, state and local health authority requirements as well as MIT and DLC specific requirements regarding COVID-19
 safety standards. This includes but is not limited to MIT Visitor Policy. See MIT Now for more information on the most up to date MIT
 Policy: https://now.mit.edu/
- For both on campus and off campus research, prior to arrival at the study site, all subjects will complete an approved COVID-19 consent form addendum: couhes.mit.edu/forms-templates. This form must be completed by the subject and reviewed by the research study staff within 24 hours prior to the subject's arrival at the study site.
- For both on campus and off campus research, any subject who indicates they have tested positive for COVID-19 within the past 2 weeks, had contact with a COVID-19 positive patient within the past 2 weeks, currently has symptoms suggestive of COVID-19, or is at high risk for severe complications from COVID-19, will be excluded from the study.
- For both on campus and off campus research, confirm that you have reviewed the COUHES COVID-19 Updates and Restart Policies posted on the COUHES Website: couhes.mit.edu/covid-19-updates.

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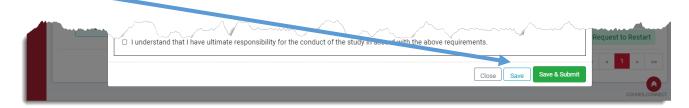


Request to Restart window: Declarations, Save & Submit



- Click the Declaration checkboxes following the attestation questions
- Click Save & Submit. (Note that only the study Principal Investigator can Submit. All others can only save.)
- If you can answer "Yes" to all questions and declarations, your study will automatically be authorized for restart.
- This Request will appear in your Approved Restart Requests list.

Use 'Save' to retain your selections and return to submit later.





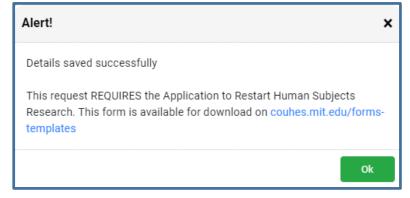


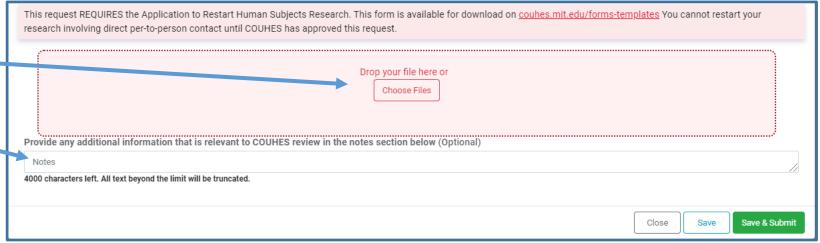
Request to Restart window: No to any Attestation requires a completed Application and COUHES approval.

 If any attestation response is "No", upon Save, an alert appears noting that you must complete and upload the Application to Restart located on the COUHES website.

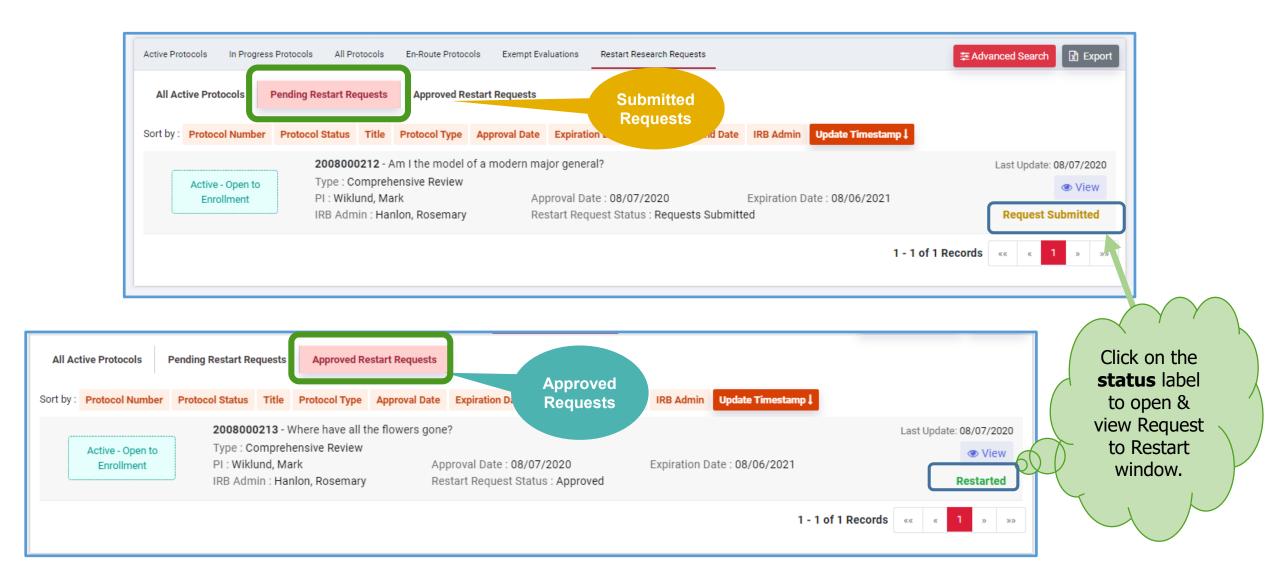
http://couhes.mit.edu/formstemplates

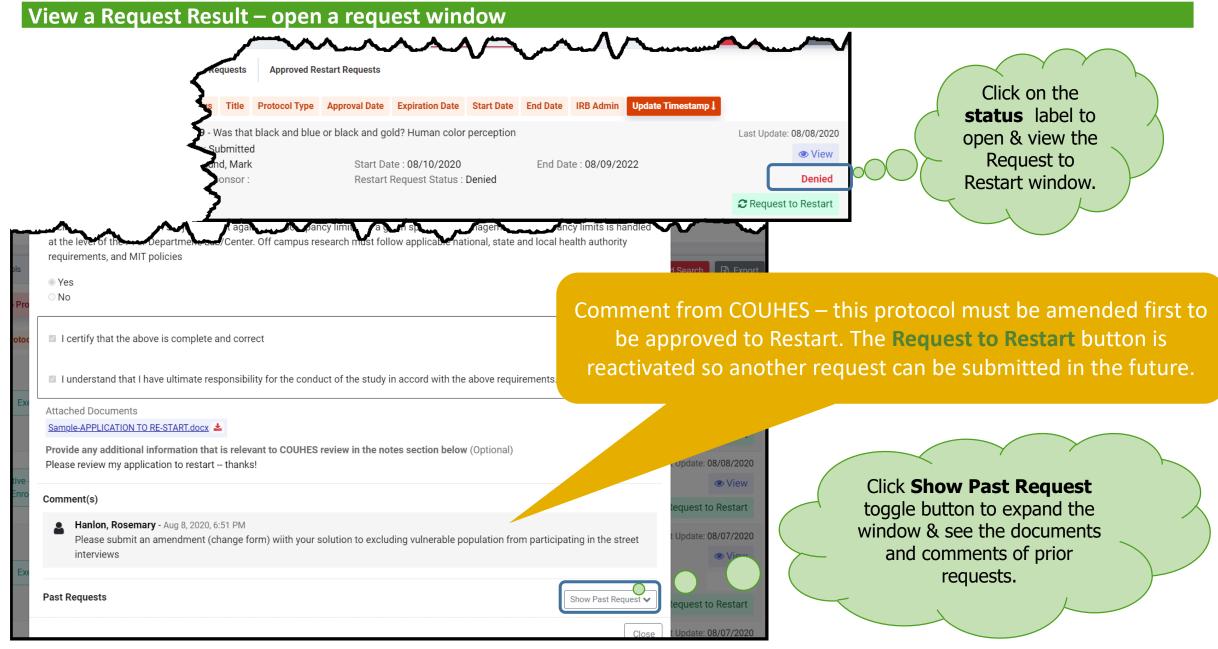
- The window will expand with a field to upload the completed application form and a field for a brief comment.
- Click Save & Submit.
- This Request will appear in your Pending Restart Requests list.



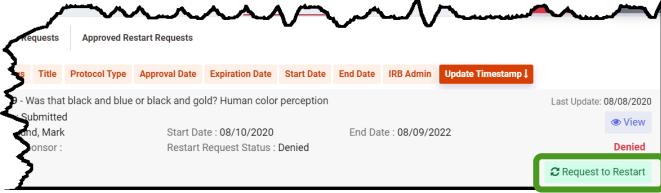


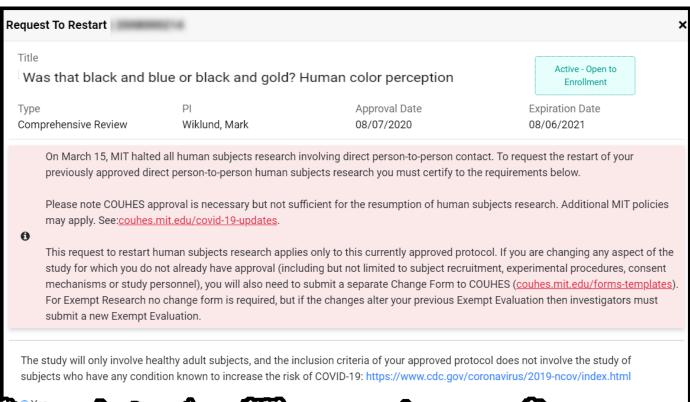
Restart Research Requests: Pending and Approved Restart Request Lists





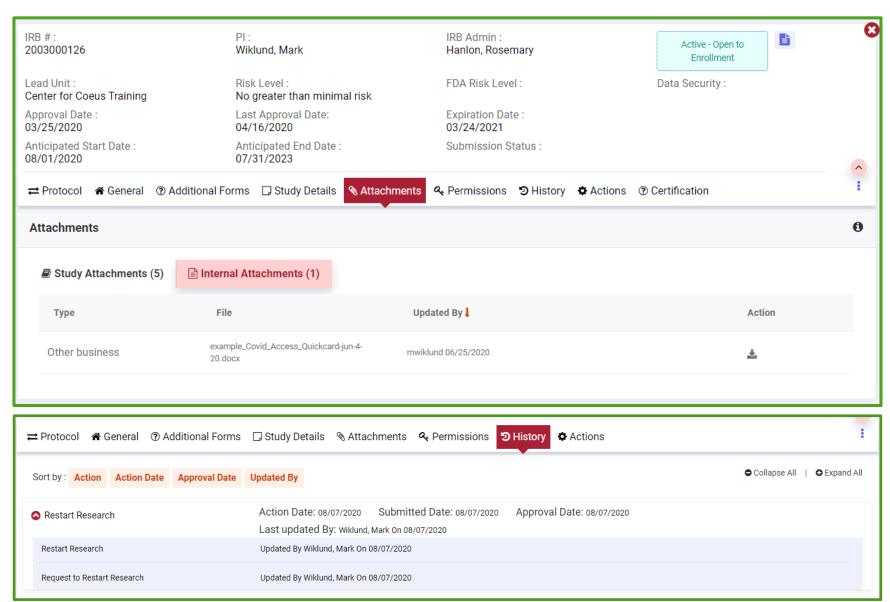
Resubmit a denied Restart Request to open and view the window





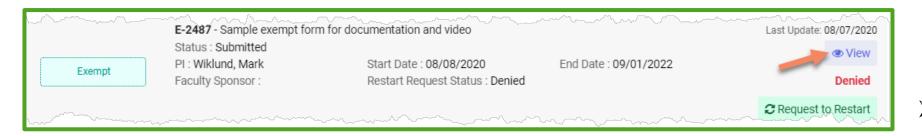
- 1. Click **Request to Restart** button on the subject protocol.
- 2. Respond to the attestations and declarations.
- 3. Click Save & Submit.

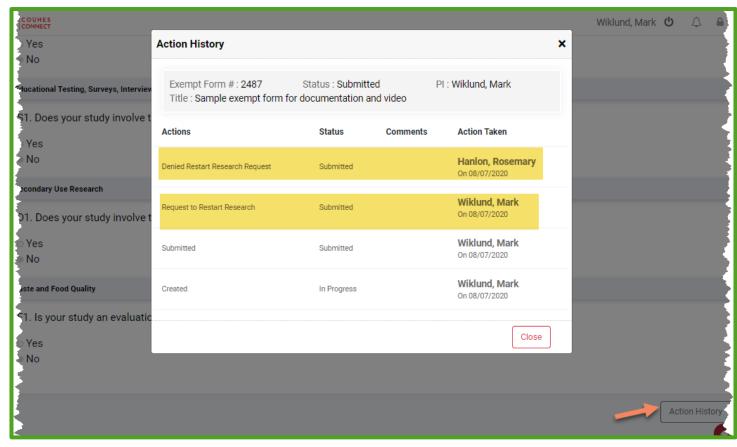
Request to Restart impact in the Protocol (attachments & history)



- Click View button to open the protocol or exempt study form.
- Click Attachments, then Internal Attachments. Restart Research requests are automatically saved here.
- Click History. Requests are logged in the protocol history.

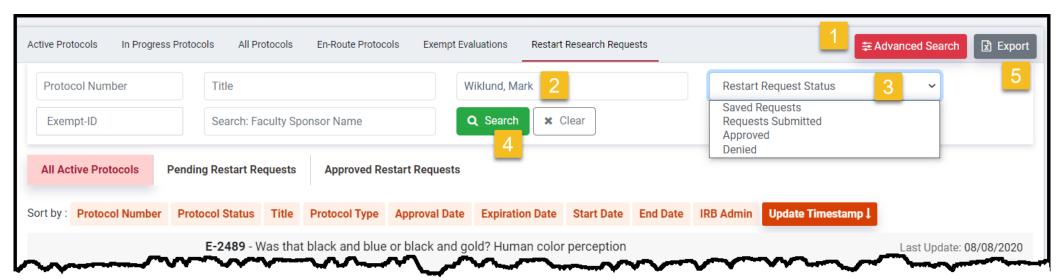
Request to Restart impact in the Exempt Determination Form (Action History)





- Click View button to open the Exempt Determination form.
- Click Action History at the bottom of the screen. Restart Research request and approve/deny date details are inserted here.
- Any attachments provided in a Submitted Request are not available in this view but are available in the Restart Research request window.

Export a list of Research to Restart



You can export a spreadsheet listing your research studies from any of the list views. For administrators monitoring many protocols for their Departments, consider using the Advanced Search to filter your results before exporting the list to your desktop. The Export tool will download the details from the list in view; so if you do use a filter, be sure to Clear it before your next Export.

Navigate to the Restart Research Requests screen.

- 1. Click Advanced Search to expand the search panel
- 2. Enter a search criteria in one of the available fields
- 3. Select a status, if desired
- 4. Click Search
- 5. Click **Export**



Email Notifications

Email notifications are sent after each of the Actions defined in the table below. Recipients are included by default, although protocol aggregators are only included if they are present in the protocol. e.g. Some protocols will have Aggregators (users able to edit) for campus users currently enrolled in the COUHES Connect pilot.

ACTION	RECIPIENTS
Request Submitted	Protocols: PI, Point of Contact(s), Aggregator(s). Exempt Determination Form: PI, Faculty Sponsor
Restart Request Approval	Protocols : PI, Point of Contact(s), Aggregator(s) Exempt Determination Form : PI, Faculty Sponsor
Restart Request Denied	Protocols : PI, Point of Contact(s), Aggregator(s) Exempt Determination Form : PI, Faculty Sponsor