COUHES Connect Quick Reference Guide

https://couhes-connect.mit.edu/connect

Exempt Evaluation Functionality

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Welcome to COUHES CONNECT Exempt Evaluation

Topics covered in this guide:

1. Create an Exempt Evaluation for a new study:
   a) Get a determination of Exempt Status
   b) Determination that the study requires a protocol for comprehensive review
   c) Determination that the study does not meet the Federal definition of human subjects research

2. View current Exempt Evaluations in pending submission & completed status

3. View the approval routing location of an evaluation

4. Approve or Reject an evaluation as Faculty Supervisor

5. View/Revisit a completed Exempt Evaluation:
   a) To review the exempt category
   b) To review the determination
Overview of Evaluation process

1. Start Exempt Evaluation
2. Read the Key Elements regarding Investigator Responsibilities
3. Enter the study details (Title, PI, Dates, Study Summary)
4. If you do not have PI status, enter a Faculty Sponsor
5. Answer the Exempt Form Questionnaire
6. Confirm your questionnaire answers to preview the determination. If the preview result is not what you expected, discuss your study responses with your faulty sponsor or a member of the COUHES Office staff – couhes@mit.edu
7. Save your evaluation if you are not ready to submit, or click Submit
8. Submit, review and agree to the confirmation certification statements
9. For users with PI Status, the determination is final
   a) If Exempt, adhere to the Investigator Responsibilities for exempt research
   b) If Not Exempt, prepare a protocol to submit for comprehensive review
10. For users without PI status, the determination is pending until approved.
    a) Evaluations entered by another user on behalf of a PI, must be approved by the PI
    b) If a Study PI does not have PI status, the evaluation must be approved by a Faculty Sponsor
    c) If the Study PI does not have PI status and there is no Faculty Sponsor, the evaluation will route to the COUHES office for approval or returned to include a Faculty Sponsor
Start Exempt Evaluation

- Navigate to COUHES Connect: [https://couhes-connect.mit.edu/connect](https://couhes-connect.mit.edu/connect)
- Click **Start Exempt Evaluation** to enter a new study for exempt determination.

Read the information on **Overview** screen and then ‘proceed’ to enter the study information or ‘cancel’ to return to the dashboard.

- There are hyperlinks in the **Overview** window that direct you to resources such as:
  - The website containing the Common Rule for the full details on the federal regulations
  - The COUHES website where MIT policies, practices, and guidelines are provided
  - The email and telephone contact details for reaching out to the COUHES office.
- You have the ability to re-display the Overview screen from the Evaluation (shown in a later next slide)
Exempt Evaluation Overview - Key Elements

- The hyperlinks embedded in the overview navigate to the full text of the Common Rule and COUHES resources.
- Click [Proceed] to begin the evaluation; you can redisplay the overview at any time (see next slide).
- Clicking the cancel button will return you to the COUHES Connect dashboard.
Exempt Evaluation Summary Info

The Evaluation begins with a few fields to summarize this study (defined next). An ID number is generated after the fields are completed and the [Continue] button is clicked.
Completing the Exempt Evaluation Summary

- **Title**: Enter the name of your research study.

- **Principal Investigator**: Defaults to logged in user; otherwise start typing a name and the elastic search will produce a list of MIT personnel for selection.

- **Department**: Defaults to that of logged in user; otherwise start typing the name of the department, lab, or center overseeing the PI and/or study.

- **Start & End Dates**: use the calendar tools to select the anticipated date range for your study, or type the dates in numerical MM/DD/YY format.

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**NOTE**: Start Date cannot be prior to today.
Completing the Exempt Evaluation Summary (cont’d)

- **Faculty Sponsor**: IF NEEDED – type in the name and make a selection from the elastic search results. Connect uses MIT appointment Titles to determine PI status. Please contact COUHES if you have questions about PI Status.

- **Summary**: Enter a brief description of your study that includes the purpose of your research and experimental procedures. Please use lay language and do not exceed 1,250 characters.

- **Continue**: Click [Continue] to save the entries and proceed to the questionnaire. **NOTE: Study PI cannot be changed after this action.**

- Warnings *may* present on PI status; you may proceed and follow up with COUHES.
Exempt Evaluations

- After clicking [Continue], the Exempt ID number and the Status tag appear.

- The Exempt Form generates below the summary section. Once you answer the first question, the next valid question appears.
Questionnaire features

- The exempt questionnaire dynamically presents a follow-up question based on your response.
- This means that a “yes” response will present a different result than a “no” response.
- Some answers prompt another question in the same category, while some answers present the next category.

Click the lightbulb icon to expand the help-text for that question. The contextual help appears in a yellow band below answer options.

The contextual help text will remain until you close it. Hover your cursor over the yellow help band to display the (x) close icon. Click the (x) to close the help text.
The Exempt Evaluation questions are presented in categories:

- General
- Prisoner Involvement
- Exempt Category 1: Research in an Educational Setting
- Exempt Category 3: Benign Behavioral Intervention
- Exempt Category 2: Educational Testing, Surveys, Interviews or Observation
- Exempt Category 4: Secondary Use Research
- Exempt Category 6: Taste and Food Quality

- If your responses in the General category determine that your study does not require review, a confirmation appears noting that your evaluation is complete.

- If your responses in the General category determine that your study may require review, the questionnaire will present the next category, until all categories are complete.

- While each question has some contextual help, more information and guidance can be found on the COUHES website (couhes.mit.edu).
Answering questionnaire questions...

Select your responses to the questions:

Exempt Category 1 – Research in an Established Education Setting
E1. Is your study conducted in a traditional educational setting (classroom, seminar, lecture, afterschool program, etc.) that involves normal educational practices?
- Yes
- No

Click in the radio button to select the answer

E2. Could the research adversely impact students’ opportunity to learn?
- Yes
- No

NOTE: Changing an answer in a prior category will erase later category answers. You must re-answer all the following categories.

Exempt Category 3 – Benign Behavioral Intervention
B1. Does your study include a benign behavioral intervention that includes data collection through verbal or written responses, or audiovisual recording?
- Yes
- No

Exempt Category 2 – Educational Testing, Surveys, Interviews or Observation
S1. Does your study involve the use of surveys, interviews, educational tests, or observation of public behavior?
- Yes
- No

You can save your Evaluation and return to revise your responses and/or complete it at a later time. Use the [Save] button at the bottom of the screen, and then [Exit] to the dashboard.
Completing your Evaluation

When all the relevant questions have been answered, a confirmation message will appear.

A green stared notice confirms your study is eligible for exempt status. You can submit now, or save and exit.

A red alert notice confirms your study is not eligible for exempt status and requires submission of a Comprehensive Review. The response(s) causing review are highlighted in pink in the designated category.

At this point, you can revise your responses, save and exit to complete later, or submit. If you revise responses, you will need to re-answer the questions in subsequent categories.
Submit your Evaluation

When ready, click [Submit]

You will be presented with a Confirmation window with a series of certification statements.

Confirm by clicking the [ ] box preceding each statement.

When all boxes are checked, the [Agree] button appears.

Click [Agree] to continue with the submission. Otherwise click [Close]
Click **[Action Log]** at the bottom of the screen to view action items.

In this example, the study Investigator does not have PI Status, so a Faculty Sponsor was added.

Upon Submission, the Faculty Sponsor is notified via email to review this evaluation.

The Faculty Sponsor can Approve, or Reject to return the evaluation to the study investigator.
Open an existing Exempt Evaluation

If you saved and closed an evaluation, you can return to complete it from your Connect Dashboard.

- To open an existing Evaluation, navigate to the **Exempt Evaluations** list.
- The default view is the **Pending** list – your evaluations that are still in progress, or are pending your approval.
- Click the [View] button to open the study.
Locating Exempt Evaluations to Review

Users are alerted to Exempt Evaluations requiring review in the following ways:

- A count appears **Pending Actions** tile and the list generated by this tile.
- **Exempt Evaluations > Pending** list: Pending Review appear, as do un-submitted evaluations.
- Email notification - system email requesting review of an evaluation where the users is PI or a sponsor.
Approve or Reject an Exempt Evaluation

Evaluations need to be approved in the following circumstances:

- Approved by the PI if another user created the evaluation on behalf of the PI.
- Approved by the Faculty Sponsor if the PI does not have PI Status.
- Approved by the COUHES office if the PI and/or Faculty Sponsor do not have PI status.

As noted previously, Connect uses the HR Appointment Title to determine PI Status. Sometimes, appointment titles are updated and do not match the current list of MIT PI Status appointment titles. Contact the COUHES office if you have questions about your PI status in Connect.

Evaluations requiring review have Approve and Reject buttons at the bottom of the screen.

- **Approve** moves the evaluation to either the next required approver or completes the review requirement.
- **Reject** returns the evaluation to in-progress status to allow the preparer to make revisions and resubmit.
Locate the evaluation in one of your Pending lists and click [View] to open it.

Review the Exempt Determination information.

Scroll down the screen to see the study summary details and the answered questions.

Select the appropriate button for your action:

**Approve**: Acknowledge and agree to the PI & Faculty Sponsor Certification Statements to produce the Approve box: enter a comment, if desired. The comment is retained in the Action Log.

**Reject**: enter a comment in the reject box, if desired. The comment is retained in the Action Log.
Generate Determination Letter

- Locate the evaluation in your My Studies list and click [View] to open it.
- Click Generate Determination to download the Determination letter.
- You can also generate the letter from the Exempt Evaluations > My Studies list screen in your Dashboard.

**Exempt Determination:**

1. **EXEMPT_CATEGORY_1**
   - Research conducted in a traditional educational setting that involves normal educational practices and does not adversely impact a students’ opportunity to learn. 45 CFR 46.104(d)(1)

2. **EXEMPT_CATEGORY_2**
   - Research involving surveys, interviews, educational tests or observation of public behavior with adults or children and disclosure of the subjects' responses outside the research could reasonably place the subjects at risk for criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation. Research activities with children must be limited to educational tests or observation of public behavior and cannot include direct intervention by the investigator. 45 CFR 46.104(d)(2)

**Key elements of Exempt Evaluation**

- View Confirmation
- Generate Determination

*The questionnaire below will help determine if your research meets the exemption criteria or if Comprehensive Review is required. Guidance is available throughout the questionnaire and on the COUHES website, visit [http://couhes.mit.edu/](http://couhes.mit.edu/). Remember, you can always save your progress and return at any time. If you would like any clarifications or further assistance, you are encouraged to contact the COUHES office.*
Questions?

- COUHES Connect website: [https://couhes-connect.mit.edu/connect](https://couhes-connect.mit.edu/connect)

- Questions about Protocols, Exempt Studies, or COUHES processes and practices, please review the materials posted on the COUHES or contact the COUHES Staff:
  - website: [couhes.mit.edu](http://couhes.mit.edu)
  - Email: [couhes@mit.edu](mailto:couhes@mit.edu)
  - Phone: 617-253-6787

- Questions regarding navigation, general functionality, or feedback on documentation, please contact [ra-help@mit.edu](mailto:ra-help@mit.edu)

- For Department IRB Administrator role assignment, please contact your Department’s Primary Financial Officer.

- For difficulties with MIT Certificates, please contact [servicedesk@mit.edu](mailto:servicedesk@mit.edu)