Quick Guide to Certification for PI's

As of the October 5, 2020 update, instead of protocols routing to the PI for approval, the PI will affirm the certification questions in each protocol submission to acknowledge the submission completeness and policy compliance.

To support the certification process the following features are now present in Connect Protocols:

- **Certification tab** with the PI's detail tile followed by the PI Certification Questions. **Only** the PI can answer.
- **Certification Completed Status** column in the Protocol personnel data and certification screen.
- **Incomplete PI Certification Warning** validation at the Submit the protocol/amendment/renewal action.
- **Incomplete PI ERROR** validation prevents a protocol from being approved by COUHES.
- **Email Certification requested notifications** contains a hyperlink directly to the item & certification screen.

For COUHES related questions, contact couhes@mit.edu  For Connect system questions, contact ra-help@mit.edu
COUHES Connect PI Certification

As the Principal Investigator of this study, I certify that the information provided in this application is complete and correct.

As the Principal Investigator, I understand that I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by COUHES.

As the Principal Investigator of this study, I agree to comply with all MIT policies, as well as all federal, state and local laws on the protection of human subjects in research, including: Ensuring all study personnel satisfactorily complete human subjects training; Performing the study according to the approved protocol; Implementing no changes in the approved study without COUHES approval; Obtaining informed consent from subjects using only the currently approved consent form; Protecting identifiable health information, to the extent required by law, in accordance with HIPAA requirements; Promptly reporting significant or untoward adverse effects.

As the Principal Investigator, I certify that I have reviewed the COVID-19 Updates and Policies (https://couhes.mit.edu/covid-19-updates) and upon COUHES approval, agree to submit a Restart Research Request.
If you attempt to Submit for Review without a completed PI Certification, a **Warning** will present.

You can proceed with the submission; an email request to certify will be generated to the PI.

**Best practice**: certify **before** submitting.

The **PI cannot return** the protocol for updates & the **protocol cannot be approved** by COUHES if the certification is incomplete.
COUHES Connect PI Certification

COUHES Connect PI Certification questions

Access to the certification is based on your role as PI: you do not need additional permissions to answer the certification.
COUHES Connect PI Certification

COUHES Connect PI Certification – accessing the certification screen

PI’s can access the protocol certification in several ways.

1. **Certification Request email** provides the easiest option – and is available **Before or After submit**. The custom hyperlink in the email notification takes you directly to your certification questions in the subject protocol document.

2. Your Connect Dashboard > **In Progress Protocols list** - Any protocol/amendment/renewal requires your certification. You can open any of these in-progress protocols in view or edit mode to access and answer the Certification Questions.

3. Your Connect Dashboard > **En-Route Protocols list** - Any protocol/amendment/renewal that is En-Route for Department Head review requires your certification. You can open these pending authorization items in view mode to access and answer the Certification questions.

4. Your Connect Dashboard > **Awaiting IRB Response** - Any protocol/amendment/renewal that is in Submitted to COUHES status can be found in your Awaiting IRB Response list – just **click the tile “Awaiting IRB Response”** to present that list. You can open any of these items in view mode to access and answer the Certification questions.
COUHES Connect PI Certification – Email

Notifications are system-generated. Periodically check your spam or junk boxes; and update your filters to accept these emails.

Custom hyperlink opens this protocol at the Certification screen

Courtesy copy sent to the Correspondence Administrator
If the protocol has just been created (initial), updated (amendment) or renewed (renewal), find it on the In Progress list.

- From your Connect Dashboard, click the In Progress Protocols list from the list-view bar.

  - Click ‘view’ to open the protocol.
  - Click on the Certification tab
  - Answer the certification questions and Save.
  - Close the protocol using the ‘x’ in the upper right corner.

Access to the certification is based on your role as PI: you do not need additional permissions to answer the certification.
COUHES Connect PI Certification – locating a protocol from your En-Route list

If the protocol is Pending Authorization from your Department Head, you will find it in your En-Route Protocols list.

• From your Connect Dashboard, click the En-Route Protocols list from the list-view bar.

• Click ‘view’ to open the protocol.
• Click on the Certification tab
• Answer the certification questions and Save.
• Close the protocol using the ‘x’ in the upper right corner.

Access to the certification is based on your role as PI: you do not need additional permissions to answer the certification.
PI Certification while in Submitted to COUHES status

COUHES Connect PI Certification – locating a protocol from your Awaiting IRB Response list

If the protocol is at COUHES (submitted to COUHES status), you will find it in your Awaiting IRB Response list.

• From your Connect Dashboard, click the TILE “Awaiting IRB Response” to generate and open that list.

  • The Awaiting IRB Response list populates with your submissions at COUHES.
  • Click ‘view’ to open the protocol.
  • Click on the Certification tab
  • Answer the certification questions and Save.
  • Close the protocol using the ‘x’ in the upper right corner.

Access to the certification is based on your role as PI: you do not need additional permissions to answer the certification.

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