Overview of features:

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.
  - A timestamp is applied when the PI certifies.
- **A quick-navigation link from the PI’s listing on the Protocol and General screen to the certification screen.**
- **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 Certification ERROR** validation prevents a protocol from being approved by COUHES.
- **Email Certification requested notifications:** (contains a hyperlink directly to the item & certification screen)
  - Tool to send certification request notice before or after submission
  - Notice automatically sent to the PI upon submit.
  - Log of all submitted requests with timestamp.

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

10-2-2020 Ver 2
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 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.
As the Principal Investigator of this study, I certify that the information provided in this application is complete and correct.

Yes, I certify that the information is complete and correct.
COUHES Connect PI Certification questions

Read, then click the boxes to confirm, then click Save in the bottom right of the window.
COUHES Connect PI Certification

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. **From 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. **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. **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.

For COUHES related questions, contact couhes@mit.edu  For Connect system questions, contact ra-help@mit.edu
Use the Send Notification tool to generate an email to the PI to review & Certify prior to submitting. The PI’s Detail tile located on the General screen > Protocol Personnel or the same detail tile on the Certification screen.

Click on the bell icon to open the Notification Log window
The Notification log window records all certification requests to the PI.

Click on Notify to send the email with the custom hyperlink to this certification.

Each request is recorded. The button updates to Notify Again.
COUHES Connect PI Certification – email notification to Certify

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

<table>
<thead>
<tr>
<th>FROM</th>
<th>SUBJECT</th>
<th>RECEIVED</th>
<th>SIZE</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:COUHES_CONNECT@MIT.EDU">COUHES_CONNECT@MIT.EDU</a></td>
<td>Certification Request for COUHES Protocol: 2009000291 - Who put the bomp in the bomp bah bomp bah bomp?</td>
<td>Thu 9/24/2020 10:03 AM</td>
<td>20 KB</td>
</tr>
<tr>
<td><a href="mailto:COUHES_CONNECT@MIT.EDU">COUHES_CONNECT@MIT.EDU</a></td>
<td>PI Certification Complete for COUHES Protocol: 2009000290 - Wiklund Summer 2020-01</td>
<td>Thu 9/24/2020 9:23 AM</td>
<td>23 KB</td>
</tr>
<tr>
<td><a href="mailto:COUHES_CONNECT@MIT.EDU">COUHES_CONNECT@MIT.EDU</a></td>
<td>Approval Request from Claypool, KaialI. to Submit Protocol for COUHES Review: 200900028</td>
<td>Thu 9/24/2020 9:23 AM</td>
<td>23 KB</td>
</tr>
</tbody>
</table>

TO: [mwiklund@mit.edu]
CC: [irinav@mit.edu]

Your certification is required to complete COUHES protocol 2009000291 – Who put the bomp in the bomp bah bomp bah bomp?.

You can complete the certification for this protocol by opening this link: https://couhes-connect-test.mit.edu/connect-qa/dashoard?protocolNumber=2009000291&sequenceNumber=0&tabName=certificationTab&personId=921189290

This is an automated courtesy notification.

PLEASE DO NOT REPLY TO THIS MESSAGE.

https://couhes.mit.edu | 617-253-6787 | couhes@mit.edu

MIT COUHES Committee on the Use of Humans as Experimental Subjects | E25-143b, 77 Mass Ave, Cambridge, MA 02139
COUHES Connect PI Certification Validation warning upon submit (October 2020)

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**: have the PI certify **before** submitting.

The **PI cannot return** the protocol for updates and the **protocol cannot be approved** by COUHES unless the PI Certifies.