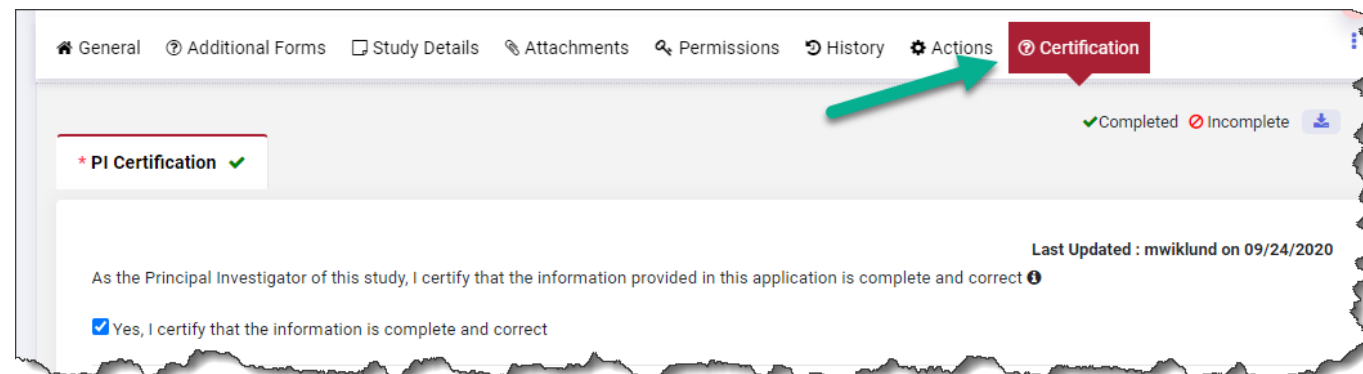


Quick Guide to Certification for PI's

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.





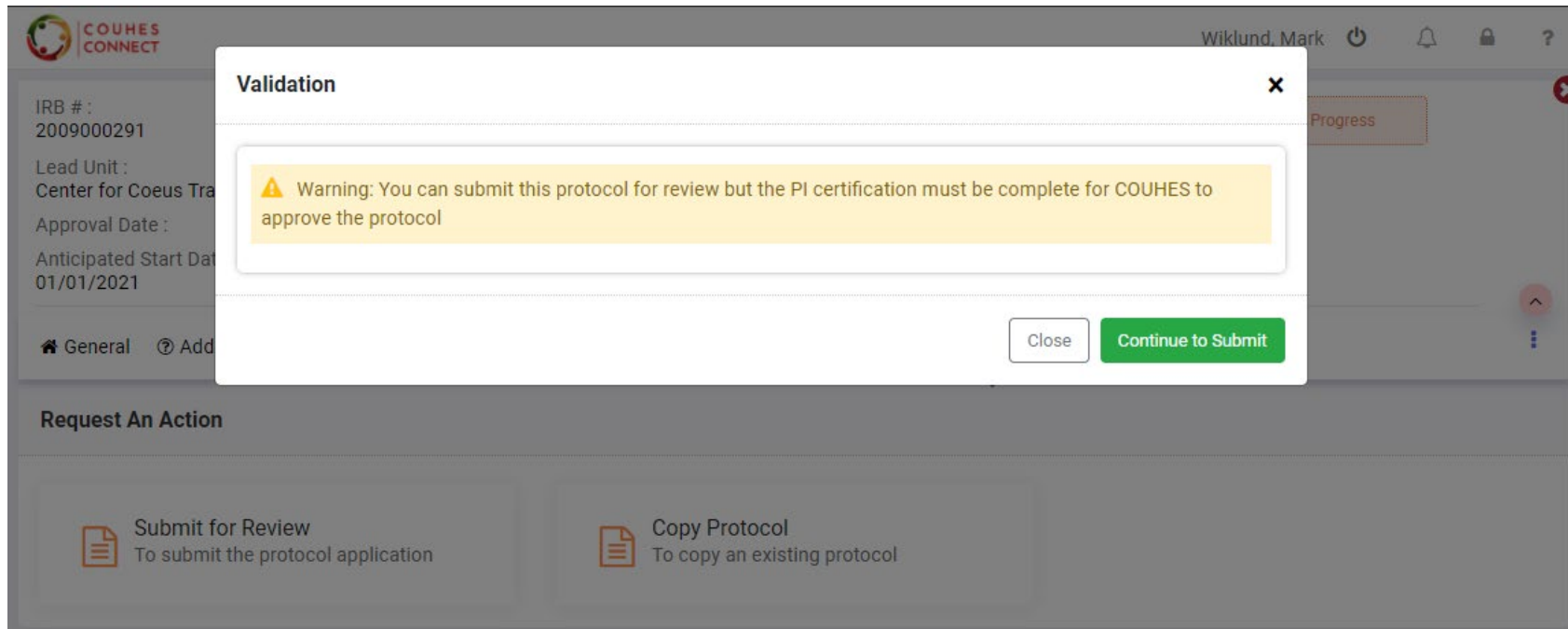
COUHES Connect PI Certification

COUHES Connect PI Certification questions October 2020

- 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.

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: 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 questions

Read, then click the boxes to confirm, then click Save in the bottom right of the window


✓ Completed ✗ Incomplete 

*** PI Certification** ✗


Last Updated : on

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

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. 

Yes, I understand I have this responsibility


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. 

Yes, I agree to comply

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. 

Yes, I certify

Save



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 – accessing the certification screen

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

BEFORE
submit for review

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.

AFTER
submit for review

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 notification to Certify

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

FROM	SUBJECT	RECEIVED	SIZE
COUHES_CONNECT@MIT.EDU	Certification Request for COUHES Protocol: 2009000291 - Who put the bomp in the bomp bah bomp bah bomp?	9:40 AM	22 KB
COUHES_CONNECT@MIT.EDU	PI Certification Complete for COUHES Protocol: 2009000290 - Wiklund Summer 2020-01	Thu 9/24/2020 10:03 AM	20 KB
COUHES_CONNECT@MIT.EDU	Approval Request from Clavpool, Kaial T. to Submit Protocol for COUHES Review: 200900028...	Thu 9/24/2020 9:23 AM	23 KB

Courtesy copy sent to the Correspondence Administrator

Custom hyperlink opens this protocol at the Certification screen

 COUHES_CONNECT@MIT.EDU | kc-notifications-test

Certification Request for COUHES Protocol: 2009000291 - Who put the bomp in the bomp bah bomp bah bomp?

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/dashboard?protocolNumber=2009000291&sequenceNumber=0&tabName=certificationTab&personId=921189290>

This is an automated courtesy notification.

PLEASE DO NOT REPLY TO THIS MESSAGE

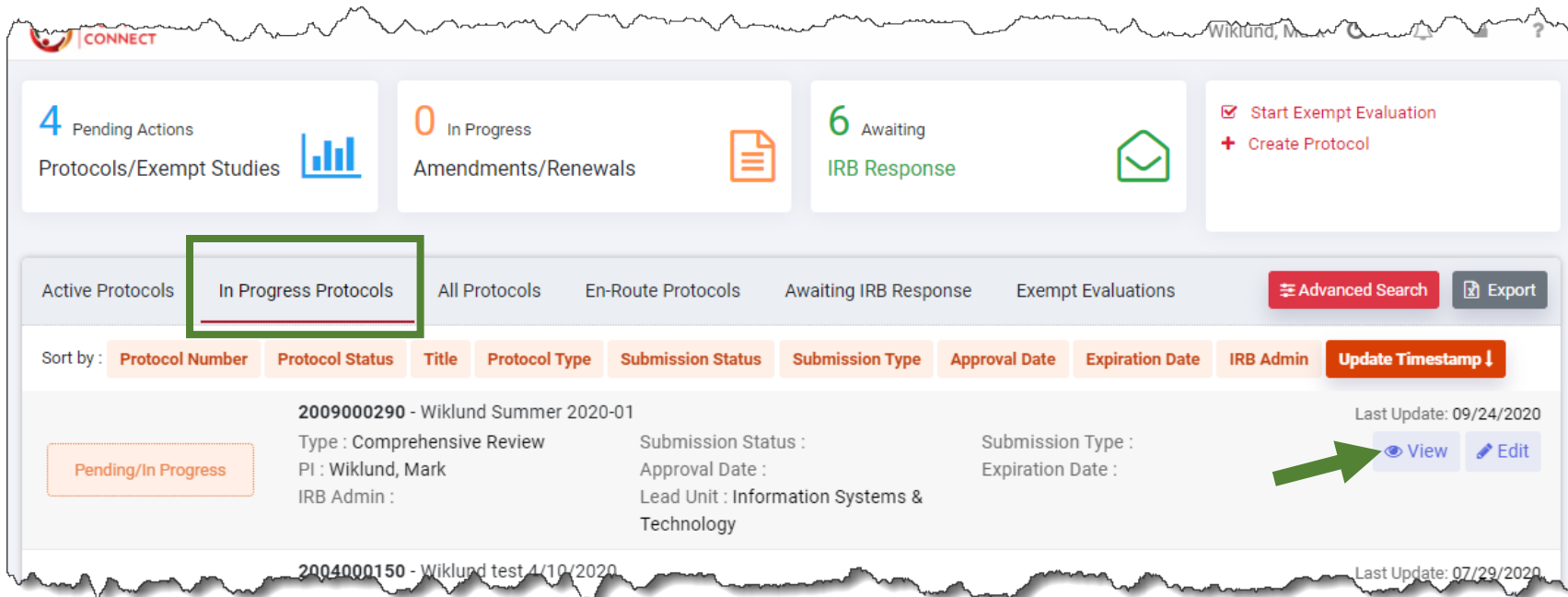
<https://couhes.mit.edu> | 617-253-6787 | couhes@mit.edu

MIT COUHES Committee on the Use of Humans as Experimental Subjects | E25-143b, 77 Mass Ave, Cambridge, MA 02139

COUHES Connect PI Certification –locating a protocol from your In Progress list

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.

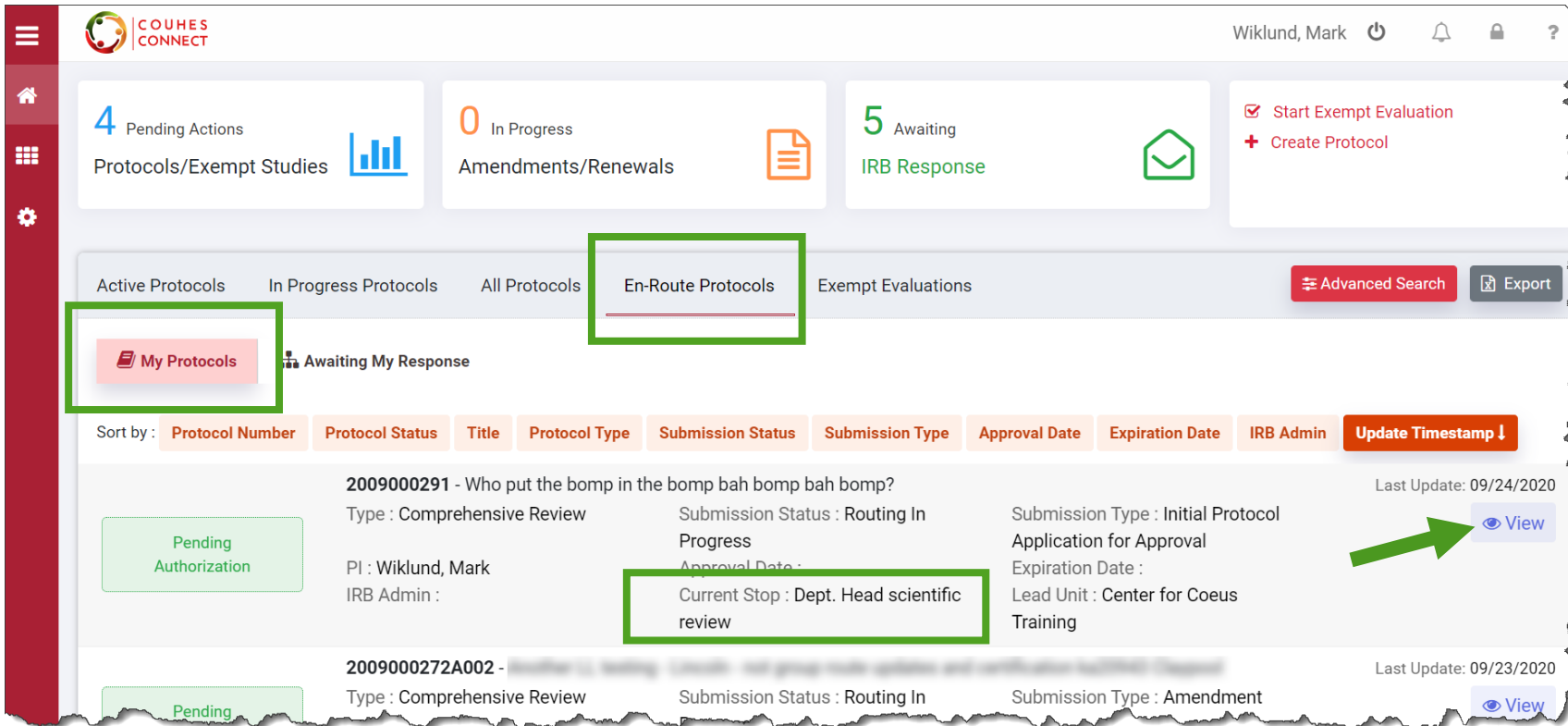
Access to the certification is based on your role as PI: you do not need additional permissions to answer the certification.

PI Certification while En-Route to Department Head

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.



The screenshot shows the COUHES Connect dashboard. The 'En-Route Protocols' tab is selected in the list-view bar. Below it, the 'My Protocols' tab is also highlighted. The main table displays a list of protocols. The first protocol, 2009000291, is in a 'Pending Authorization' status. A green box highlights the 'Current Stop : Dept. Head scientific review' field. A green arrow points to the 'View' button in the upper right corner of the protocol entry.

Protocol Number	Protocol Status	Title	Protocol Type	Submission Status	Submission Type	Approval Date	Expiration Date	IRB Admin	Update Timestamp
2009000291	Pending Authorization	Who put the bomp in the bomp bah bomp bah bomp?	Comprehensive Review	Routing In Progress	Initial Protocol Application for Approval			Wiklund, Mark	09/24/2020
2009000272A002	Pending		Comprehensive Review	Routing In	Amendment				09/23/2020

- 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.

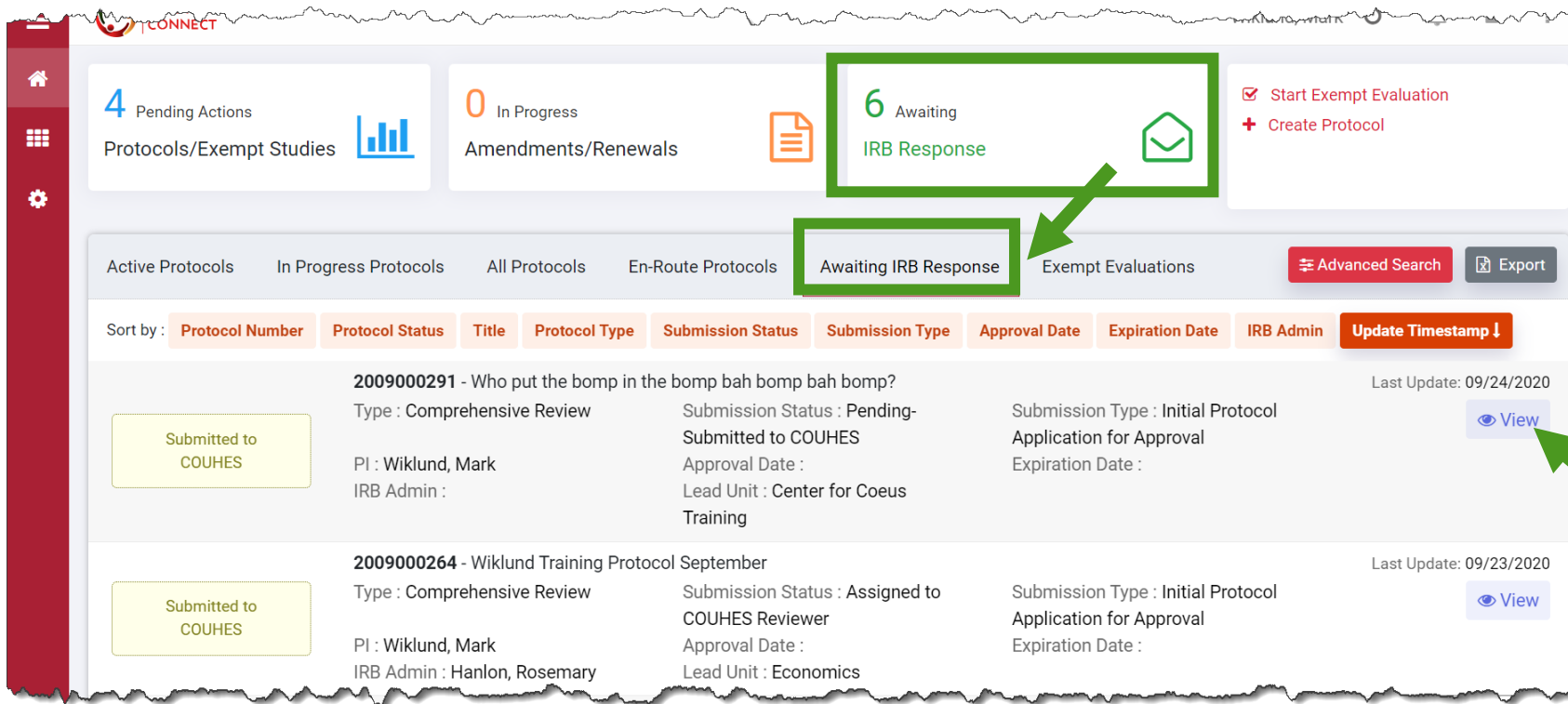
Access to the certification is based on your role as PI: you do not need additional permissions to answer the certification.

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 screenshot shows the COUHES Connect dashboard. At the top, there are four summary tiles: '4 Pending Actions Protocols/Exempt Studies', '0 In Progress Amendments/Renewals', '6 Awaiting IRB Response' (highlighted with a green box), and 'Start Exempt Evaluation' and 'Create Protocol' buttons. Below these is a navigation bar with tabs for 'Active Protocols', 'In Progress Protocols', 'All Protocols', 'En-Route Protocols', 'Awaiting IRB Response' (highlighted with a green box), and 'Exempt Evaluations'. There are also 'Advanced Search' and 'Export' buttons. Below the navigation bar is a table of protocols with columns for 'Sort by', 'Protocol Number', 'Protocol Status', 'Title', 'Protocol Type', 'Submission Status', 'Submission Type', 'Approval Date', 'Expiration Date', 'IRB Admin', and 'Update Timestamp'. Two protocols are listed, both with a 'Submitted to COUHES' status. The 'View' button for the first protocol is highlighted with a green arrow.

- 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.


COUHES Connect PI Certification questions

Read, then click the boxes to confirm, then click Save in the bottom right of the window


✓ Completed ✗ Incomplete 

* PI Certification ✗


Last Updated : on

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Yes, I certify

Save



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