

HCCRC Protocol Review Process

In order to use ETU services, protocols MUST apply through:

<https://protocolreview.catalyst.harvard.edu>

General Access/Notification Guidelines to Submit Protocols:

1. If user's first time using HCCRC Protocol review system, Harvard eCommons ID must be obtained
 - a. To obtain eCommons ID, please visit: <https://ecommons.med.harvard.edu/> and follow the registration instructions
2. Once eCommons ID has been obtained, you will need to create an account with the protocol review system (<https://protocolreview.catalyst.harvard.edu>) and log in using the eCommons credentials. Once you are logged into the system, fill out your email address and institution.
3. Once registered in system, Investigator or Study Team can begin submitting protocols.

Protocol Review Process:

1. Once the protocol and CHERP application have been submitted, the protocol review process can begin by assigning the four sections that need to be reviewed. These four sections can happen simultaneously:
 - a. ETU Admin review
 - b. ETU Nursing review
 - c. ETU Nutrition review
 - d. Scientific Review
2. **Admin Review**: Admin review will check for proper documentation, which includes:
 - a. IRB documents from reviewers IRB
 - b. Summary statement (if NIH funded)
 - c. Funding statement for approved foundations
 - d. Sponsor protocol/multicenter consortium protocol
 - e. Investigator drug brochure
3. **Nursing Review**: Nursing review is completed by the ETU nursing team
4. **Nutrition Review**: Nutrition review is handled by the ETU nutrition team
5. **Scientific Review**: The funding source will determine the scientific review path. There are four types of scientific review:
 - a. **No Scientific Review**
 - i. Protocols that are funded via the sources below do not need scientific review:
 1. Multicenter Consortium
 2. Peer reviewed in NIH format with summary statement
 3. Industry initiated

4. Harvard Catalyst funded pilot grants
 5. Harvard Catalyst funded training grants that have been reviewed
 6. Foundations with rigorous peer review (check with Michelle Beck)
- ii. “No Scientific Review” protocols should be completed in 5 business days

b. Streamline Review

- i. When a protocol is minimal risk and requires minimal ICCTR resources (for example, requesting LabCorp pricing, lab processing, blood draw, etc.) it can go through a streamline review.
- ii. ICCTR MRO will conduct Scientific Review. No external review necessary.
- iii. “Streamline Review” protocols should be completed in 10 business days

c. Full Scientific Review

- i. Protocols that require full scientific reviews include, but not limited to, unfunded projects or PI initiated with industry support
- ii. If Full Scientific Review is needed, Harvard Catalyst will assign two external reviewers.
- iii. “Full Scientific Review” protocols will take no less than 10 business days but can take up to a month if the Reviewers need further clarification or updates on the protocol are needed.

d. Gene Therapy Scientific Review

- i. Regardless of funding, gene therapy protocols must undergo scientific review
- ii. Study team submits the protocol via HCCRC protocol system and Gene Therapy group at BCH will undergo the scientific review outside of the system.
- iii. Gene Therapy reviews will take no less than 10 business days but can take up to a month if the Reviewers need further clarification or updates on the protocol are needed.

Approval Letter Process:

1. Once the protocol has been approved for HCCRC resources (completed Admin, Nursing, Nutrition, and Scientific Reviews), protocol will be sent along to ICCTR CMO for final approval and signature.
2. Once signed, the approval letter will be uploaded into CHERP, HCCRC website, and an email will be sent to the Investigator and study team coordinator. This will complete the process.

Catalyst Amendment Scientific Review

The following process is used when there is an amendment to the protocol after approval

1. Study team sends ICCTR admin the proposed amendment
2. ICCTR admin sends amendment to Program Director who determines if the amendment requires scientific review. If so, Program Director will conduct scientific review or ask admin to do the following:
 - a. If a scientific review is needed for the amendment and the protocol has had a full Catalyst scientific review, ICCTR admin sends amendment to original reviewers.
 - b. If a scientific review is needed for the amendment and the protocol did not receive a full Catalyst scientific review, ICCTR admin will check with study team to see if it has received departmental scientific review
 - i. The departmental scientific review will give final approval
 - c. If scientific review for amendment is not needed, ICCTR admin will let the study team know