

Center for Human Phenomic Science

New Submission

Center for Human and Phenomic Science (CHPS) applications are linked to eIRB. IRB studies using CHPS will have the same study protocol number (IRB number). To request service from CHPS, start in the IRB workspace.

- New eCHPS submissions begin in eIRB application with Section 1.03 (3.0). Responding “YES” indicating you are requesting CHPS resources automatically creates an eCHPS application with the same IRB number. This is the same method you would use for an already IRB approved study that seeks to add CHPS services. The only difference is that you would be doing this as an IRB amendment (AMD) first. Once the IRB approves the AMD, the CHPS application will be available to you.

1.03 New Study Type

3.0 * Is the Investigator requesting CHPS resources?

- If you respond YES at this time, an eCHPS study will be created.
- After completing your IRB submission (which prepopulates much of the CHPS submission), go to the CHPS link to apply for CHPS services.
- If you respond NO at this time, but later require CHPS resources, you will need to create an IRB amendment to create the CHPS link to apply for CHPS services.

Yes No

- For Cooperative Review studies, answer “yes” on Section 1.06 Reliance Agreements:

4.0 * Is the Investigator requesting CHPS resources?

Yes No

- Once the eCHPS workspace is opened, you can edit the CHPS study to begin completing the eCHPS application.
- We ask that you fill out each of the pages. Note: questions with red asterisks are required.
- Many fields are auto-populated from the eIRB module and will not need to be entered twice.
- Reach out to the CHPS Administrative Staff for any questions or assistance with the eCHPS application.
- Once the eCHPS application is completed and submitted, CTFM will use SIFTER to build the study budget in order to initiate OnCore for budgeting and the study calendar.

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- The submitted CHPS protocol will be reviewed by the Directors of the Cores being requested and then at our monthly Resource Committee.
- After you submit the CHPS study, check your eCHPS workspace for any correspondence and the status of your study. Studies must receive both IRB and CHPS approval before Core services can be utilized.
- Once the study receives IRB and CHPS approval, we ask you to schedule a start-up meeting with each CHPSs Core you will be using prior to scheduling any participants for study visits.

CHPS Amendment

Often a change in study design and/or services will also require an IRB amendment. Please check with the IRB to see if an amendment is needed.

To start a CHPS amendment, go to an approved protocol's workspace, at the bottom of the left-hand navigation bar, select "New Amendment."

Please note this is a two-step process:

- Step 1: Please complete the amendment form, then hit "FINISH." The details of study procedures and changes here provide an *overview* of what is requested. The information must be added to the study application in order to be reviewed.
- Once the eCHPS amendment form is finished, please select "Edit Modified Study" on the top left to make the specific changes to your study application and to update/change request for Core services. Be sure to do section 3.01 to update numbers of visits. Then check off 4.01 for any new cores. Lastly, update the individual core section with the changes requested.
- Once the eCHPS application has been updated, submit the amendment for review.
- The request will be reviewed by the CHPS Core Directors being requested and then by the Resource Committee at the monthly meeting.

An eCHPS amendment may also affect the study budget (e.g. additional services or visits). Budget amendments are submitted through SIFTER. A corresponding OnCore budget amendment should be created as well. If you have any questions regarding a budget amendment, please email CTFM@chop.edu (link sends e-mail). Also update your OnCore as needed.



**Children's Hospital
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CHPS Continuing Review

1. Studies approved by the CHOP IRB:
 - For studies approved by the CHOP IRB that have a specified expiration date, Continuing Reviews (CR) are linked between IRB and CHPS. Opening an IRB continuing review will create an eCHPS continuing review if there is an approved request for CHPS resources.
 - With the IRB and CHPS CRs linked, many of the sections are filled with the eIRB submission. Complete the CHPS CR application and submit.
 - NOTE: Although creating the CR is linked to the IRB, CHPS CR submission and review is a separate activity from eIRB.

2. Cooperative Agreement IRB studies or protocols:
 - Annual CHPS CR is still required. The CHPS administrative team will need to open the CR manually for the study team in the eCHPS workspace to complete.
 - Once the eCHPS CR is created, the study team will select “Edit Continuing Review” within the eCHPS workspace to open the CR and complete the questions on the first page.
 - For question 3: please attach a copy of the most recent Cooperative IRB approval letter and a brief progress report highlighting if enrollment is still open; visits are still being scheduled; or sample storage status

3. Studies following the 2018 Common Rule (No IRB CR needed)
 - Annual CHPS CR is still required. The CHPS administrative team will need to open the CR manually for the study team in the eCHPS workspace to complete.
 - Once the eCHPS CR is created, the study team will select “Edit Continuing Review” within the eCHPS workspace to open the CR and complete the questions on the first page.
 - For question 3: please attach a brief progress report highlighting if enrollment is still open; visits are still being scheduled; or sample storage status



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Once the CR is completed, please submit for CHPS review. The request will be reviewed by the Directors of the Cores being utilized and our Resource Committee.

CHPS Study Review Process

CHPS holds monthly Resource Committee meetings where all requests for our resources are reviewed. This includes new studies for CHPS, CHPS Amendments, and CHPS Continuing Reviews. The meeting is usually held on the second Tuesday of the month. Research studies cannot utilize CHPS until they receive both IRB and CHPS approval.

CHPS will consider expedited study approvals under certain circumstances:

- Compassionate use, e.g., use of a potentially life-saving drug in a patient who is desperately ill.
- Circumstances in which a brief opportunity to capture a rare patient population/circumstance could not be predicted in advance.
- Under rare circumstances, if data are needed urgently due to grant submission or expiration dates, and if substantiated reasons for not submitting the CHPS proposal in a timely manner are provided.

For additional information, please contact the CHPS Administrative Staff.

Questions?

Please contact the CHPS administrative team if you need support:

- John Krall, administrative director, krallj@chop.edu
- Eileen Ford, administrative manager, forde@chop.edu
- Beth Schwartzman, clinical research project manager, schwartzmann@chop.edu