FAQs by Topic
Introduction

We have posted our IRB process related FAQs in a searchable PDF format. You may search by using the CTRL/F key combination. Just type the search word in the box that appears. You may also scroll through the Table of Contents and click on the topic or question of interest.

The FAQs are broken into 4 categories: General Topics; PHIRST (our electronic application system); Student Information; and CITI.

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Amendments and Progress Reports

1. How do I submit an amendment request?

It depends on the nature of the changes. Please visit the JHSPH IRB website at www.jhsph.irb.edu for the Guidance for Submitting Research Changes to the IRB.

- Making minor changes to already approved instruments and recruitment materials only that are (1) consistent with the original aims of the study and (2) do not increase risk to subjects? If so, you can use our Administrative Amendment Application for Minor Changes to Research application.

- Adding a new phase, revising the research plan, submitting a revised consent form, and/or making more substantive changes than those described under the Guidance for Submitting Research Changes to the IRB? If so, then complete an Amendment Application, and follow the guidance below:
  1. If you are revising already approved study documents, like the research plan, you must include a tracked and clean copy of the revised document.
  2. If you are submitting a new/revised consent form, please use the current consent form templates available on the IRB website and email the new consent form with the Amendment Application to jhsph.irboffice@jhu.edu. The IRB will need an electronic version of the consent form for the approval and logo process.
  3. If you are adding new study team members, submit an investigator agreement signed by each person being added; and human subjects training certificate for each person being added.

We prefer that all amendment requests be submitted via email to jhsph.irboffice@jhu.edu. We can accept an unsigned copy of the amendment request form if the amendment request is sent from the PI’s inbox or if the PI provides a separate email confirming submission of the amendment request. Otherwise, please include an authentic digitally signed copy of the amendment request, scanned signed copy of the amendment, or indicate that you will send a signed hardcopy. If you cannot submit the application electronically, we will accept a hard copy version at the IRB office at 615 Wolfe St., Suite E1100. Note: PHIRST does not handle amendments at this time.

If you need more information on submitting an amendment, please contact us.
2. **What documents do I need to submit with an amendment request?**

It depends on the nature of the changes. Please refer to FAQ No. 1, “How do I submit an amendment request?” for more information.

3. **How can I check on the status of an amendment submission?**

You can check the status of an amendment through the IRB Database. When you enter your study name, or find it under your last name, look at the bottom of the listing for the entry titled “Amendment”. If there is a “yes” beside that entry, click on it and it will lead you to a list of amendments within your study.

4. **How do I submit a progress report?**

We prefer that all progress reports be submitted via email to jhsphirboffice@jhu.edu. If you cannot send the report in electronically, submit a hardcopy to Suite E1100. Note: PHIRST does not handle progress reports at this time. We can accept an unsigned copy of the progress report if the progress report is sent from the PI’s inbox or if the PI provides a separate email confirming submission of the progress report. Otherwise, please include an authentic digitally signed copy, scanned signed copy, or indicate that you will send a signed hardcopy. Things to remember when submitting a progress report:

1. Always use the most current program report template available on the IRB website. We will return progress reports that use out of date forms.
2. If you are actively enrolling subjects in your study, please consider converting to our perpetual consent form if you have not already done so.
3. If you have enrolled subjects using a written consent process since the last approval, submit a copy of a signed and dated consent form (please redact the name) so we may verify that you are using the correct version.
4. When listing co-investigators and student investigators on the progress report, please double check the IRB Database to make sure your list matches our records. If you find any discrepancies, please submit an Amendment Application to add/remove anyone who should/should not be listed.
5. If you have had any administrative/minor departures from the IRB-approved study which do not affect the scientific soundness of the research plan or the rights, safety, or welfare of human subjects, please report these as protocol deviations when you submit your progress report using the Protocol Deviation Summary Form.
6. If you have had any anticipated problems/events that have been described in the research plan, consent form, and/or investigator’s brochure, please report these when you submit your progress report using the Anticipated Problem/Event Summary Form.
7. If any other IRBs review your study and have provided an updated approval letter, please be sure to include these with your submission.
8. If you have a Data Safety Monitoring Board, please attach a copy of the last report.

9. If you think any of the information you are providing in your progress report will raise questions with the reviewer (such as discrepancies between last year’s enrollment numbers and this year’s enrollment numbers), please include a comment in Section H of the progress report.

If you need more information on submitting a progress report, please contact us.

5. **How can I check on the status of a progress report submission?**

You can check the status of a progress report through the IRB Database. If the approval date and expiration date have been updated, the progress report has been processed. If not, assume it is still in review and contact us with your specific question.

6. **I didn’t submit my progress report in time and my study approval lapsed. What should I do now?**

If you did not submit a progress report before the study approval lapsed, all research activity including enrollment, collection of follow-up data from subjects, study visits, and data analysis must stop immediately. The IRB does not have the authority under the regulations to grant any kind of extension. To continue the study, you will need to submit for IRB review a new PHIRST application.

7. **I submitted my progress report on the day it expired and it may not be reviewed for a few days. What should I do in the meantime?**

If you have subjects in the study who are receiving a therapeutic intervention, you must request permission from the IRB to continue study activity with currently enrolled subjects. With this request, you must provide a rationale as to why it is in the subjects' best interests and ethically justified to continue study intervention during the period of IRB review. If the IRB grants the request, new enrollment, and data analysis may not occur during this time.

If your study does not involve a therapeutic intervention, all research activity including enrollment, collection of follow-up data from subjects, study visits, and data analysis must stop until the study is re-approved.

8. **Do I need to submit a signed copy of the amendment/progress report or is an unsigned emailed copy OK?**

We will accept an unsigned emailed amendment/progress report submission if the submission is sent from the PI’s inbox OR the PI provides a separate email confirming submission of the amendment/progress report. Simply copying the PI on an unsigned
emailed amendment/progress report submission is NOT acceptable. We will also accept a signed hardcopy, authentic digitally signed electronic copy, or scanned signed (pdf) copy.

9. **Can a co-investigator or student investigator sign the amendment/progress report or must it always be the PI?**

No, an amendment request or progress report must always be signed/submitted by the PI. See FAQ #8 for additional information “Do I need to submit a signed copy of the amendment/progress report or is an unsigned emailed copy OK?”

**Cancer Research**

10. **Does my application require SKCCC review?**

The SKCCC is the Sidney Kimmel Comprehensive Cancer Center. The SKCCC must, as part of its CORE grant, review all cancer-related studies that take place at Johns Hopkins. If you submit a cancer-related new application to the IRB and have not had SKCCC review, we will flag your application and notify the contact person at SKCCC for further guidance. If you obtain SKCCC approval prior to submitting your new application, you can upload a copy of your approval notice in PHIRST. The SKCCC website can be accessed here: [http://cro.onc.jhmi.edu/](http://cro.onc.jhmi.edu/).

**Categories of Review**

11. **Why isn’t my new application exempt?**

The IRB has put in place more stringent policies than those in the federal regulations for exempt studies. For example, there are some survey studies that could qualify as exempt under the federal regulations. However, because of the nature of the questions or the location of the study, the IRB has chosen to have these studies reviewed by IRB-X to provide an extra layer of protection. If your new application is reviewed by IRB-X, there is a chance that it could then be determined to be exempt from further review (meaning you would not have to submit a progress report every year). You will always receive documentation of the determination made by the IRB.

12. **What is the difference between full, expedited, and exempt review?**

The Institutional Review Board (IRB) Office is composed of an exempt team, IRB-X, and IRB-FC. The Chairs of the two IRBs work with dedicated IRB-X or IRB-FC staff. Both IRB-X and IRB-FC meet weekly. An “expedited” review process simply means that a submission to the IRB may be reviewed by a single individual rather than by the whole
board. It does not mean “fast”. IRB-X and IRB-FC perform both full board and expedited review processes.

IRB-X handles minimal risk studies that meet the expedited categories listed in the federal regulations [https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html). All IRB-X new applications receive full board review, meaning that the entire board reviews the study and makes a decision about the outcome of that review. Most IRB-X progress reports receive expedited review. Typically, most IRB-X amendments receive expedited review; however, if a new phase of the study is being added or substantial changes are being requested, the amendment will receive full board review.

IRB-FC reviews studies that pose more than minimal risk to subjects. That risk may be physical, emotional, psychological, economic, social, or legal. Because there are M.D. members on IRB-FC, and not on IRB-X, IRB-FC may review some studies which otherwise may qualify as minimal risk studies, but involve minor medical or drug interventions which require medical or P&T expertise as part of the review. IRB-FC also handles data coordinating center studies. All IRB-FC new applications receive full board review. Typically, all IRB-FC progress reports receive full board review until they reach the data analysis phase or are permanently closed to enrollment and follow up. IRB-FC amendments will receive full board review, unless they involve administrative or minor changes to the approved research.

The exempt team reviews submissions which meet the criteria for “public health practice/not research”, “not human subjects research”, “not engaged in human subjects research” and exempt studies. This team will determine whether the Principal Investigator (PI) is “engaged in human subjects research” under OHRP guidance. The PIs of all such submissions will receive documentation of these determinations.
HIPAA

13. Who do I contact if I have questions about whether the study falls under HIPAA regulations?

The IRB Office has assumed responsibility for JHSPH HIPAA & Research compliance. If you have questions about HIPAA regulations, please contact the JHSPH IRB Office at 410-955-3193 or jhsph.irboffice@jhu.edu.

14. How can I take HIPAA training?

All JHSPH investigators, study staff, and students using Protected Health Information in research must complete HIPAA training: MyLearning Module: HIPAA for Research – 01. You will find this course in the MyLearning Course Catalog under “Compliance > Research Compliance and Ethics > HIPAA & Research.” It will NOT be listed under “HIPAA”.

15. How can I upload my HIPAA training certificate to PHIRST?

After completing the HIPAA for Research course and printing out the certificate, PHIRST registered users may upload their HIPAA training certificates in their PHIRST account. To upload a copy of your HIPAA certificate, please follow these instructions:

1. Go to the Log-in page of the PHIRST website: http://phirst.jhsph.edu/
2. Enter your user ID and password
3. Click on your name at the top right side of the study workspace screen (Note: It’s right next to the ‘My Home’ icon)
4. Scroll down the page to the ‘HIPAA Training Certificate’ section.
5. Click the [ADD] button to upload your HIPAA Training Certificate
6. Click [APPLY]
7. Close your PHIRST screen.
IRB Actions

16. What does “tabled” mean?

Tabled is an action taken by the Board or a single reviewer (in cases where the submission is being reviewed in an expedited fashion). Tabled means that the Board or reviewer requires additional information before a decision can be made regarding your submission. If your submission is tabled, you will receive a memo from the IRB listing the items that need to be addressed. You should respond to this memo as soon as possible to keep the review process going.

17. What does “approved with administrative changes” mean?

Approved with administrative changes is an action taken by the Board or a single reviewer (in cases where the submission is being reviewed in an expedited fashion). Approved with administrative changes means the Board or reviewer has approved the submission pending minor changes. If your submission is approved with administrative changes, you will receive a memo from the IRB listing the administrative changes. The IRB will not release your approval notice and approved documents until you respond to the items specified in that memo, and your response is accepted. Typically, your response to the memo will be reviewed by an IRB staff member. Do not start your study until you have received the actual approval notice and approved documents.

IRB Resources

18. I only have a paper copy of a document and need an electronic copy for a submission. Does the IRB have a scanner I can use?

Yes, you can come down to the IRB Office (Suite E1100) and we can scan a document for you.

Miscellaneous

19. How can I find out which specialist has been assigned to my submission?

It depends on whether this is a new application submission or a submission for an already approved study.

Is this a new application? Sign into the PHIRST system and look up the new application in question. You should see a field with the assigned specialist’s name at the top of the screen.
Is this a submission for an already approved study? You can find out which specialist has been assigned to your submission through the IRB Database. Please note that this may not be current until 1-2 business days after we receive your submission.

If you do not have an active submission, the person listed as the specialist is the last person who worked on your study and may not be the person who works on your next submission.

20. How can I print a list of all studies by investigator?

You can print a list of all studies by investigator through the IRB Database.

21. Do I need to use the stamped instrument in the field or can I keep the stamped instrument on file and use an unstamped approved copy?

You do not have to use the stamped instrument in the field. You do, however, have to keep a stamped copy on file and use the approved version in the field. Study instruments do not require the IRB watermarking unless required by the Sponsor.

22. Why are my approved instruments not stamped?

The IRB Office does not stamp instruments unless required by the sponsor. The approved instruments will be listed in the final approval memo as confirmation of their review and approval.

23. What information should be included in a letter of support/collaboration?

The letter of support/collaboration should include the name of the organization/investigators that will be collaborating with you, description of their involvement, and agreement to collaborate with you.

Planning Phase Review

24. I have a “just in time” request from a funding agency that asks for human subjects approval, but I don’t have anything developed yet. How do I submit a planning phase? How long does it take for a planning phase to be reviewed?

The planning phase application is embedded in the main study application in PHIRST. To submit a planning phase, you need to start a new application in PHIRST. In the Study Identification section in PHIRST, which should be the first screen you are brought to, you will need to answer all of the questions and make sure that you check the box next to question 10.0 that asks if you are submitting a planning phase. This will dictate the next
screens you will be directed to within PHIRST. The next screen you come to will ask you to describe why you need the planning phase and the duration of the planning phase. You will then be taken to the Funding and Conflict of Interest section. Please be sure to upload your grant/contract in this section.

Planning phase reviews are usually completed within a few days depending on the completeness of the submission and the timing of the submission. Senior IRB staff may approve these applications. Please note that no human subjects contact may occur through a planning phase submission. You will receive a planning phase review notice through PHIRST once the review is complete.

25. Can I amend a planning phase application?

No, you cannot amend a planning phase. Prior to enrolling human subjects, you need to submit a new application in PHIRST.

26. How can I request for an extension of approval for a Planning Phase?

If the Planning Phase is to continue beyond one year, the PI must submit a written request for an extension to the JHSPH IRB Office at jhsph.irboffice@jhu.edu or via hard copy to JHSPH IRB Office, E1100 prior to the Planning Phase expiration. In the memo, include a description of the progress made to date and the reason for the extension request. An email from the PI’s email address is sufficient, though the office will accept a signed paper copy delivered to the JHSPH IRB Office. All electronic requests must come directly from the PIs mailbox or a confirmation from the PI must accompany the request.

Training

24. Do I need human subjects training?

All investigators, including students, who are “engaged in research” need human subjects training. JHSPH investigators must take CITI. Investigators from other institutions may submit their institution specific training certificate.

25. I need to provide human subjects training to my field workers and they will not have access to a computer. Can you recommend a training resource I can use?

The IRB developed an Ethics Field Training Guide (http://www.jhsph.edu/offices-and-services/institutional-review-board/training/field-training-guides-for-data-collectors/index.html) for use with data collectors and other non-professionals. It has been translated into a number of languages.
Translations

26. What forms need to be translated?

At a minimum, we require all consent-related documents to be translated. This could include telephone scripts, if consent is obtained over the phone. To save yourself time and money, you should wait to translate your consent documents until after the IRB approves the English versions. Once the IRB approves your English consent forms, we will request that you submit the translated versions with a Certificate of Translation. If you would like to have us stamp other translated documents (such as instruments), you will need to submit the translated document with a Certificate of Translation.

27. Who can translate documents and who can sign the certificate of translation?

Anyone that is fluent in the native language can translate the documents and sign the certificate of translation. The PI for the study may also sign the certificate of translation.

Turnaround Time

28. How much time does it take to receive IRB approval of a new application?

This is not an easy question to answer as there are many variables that impact review time, such as when the new application is submitted, how complete the submission is, and which committee the new application is assigned to. Typically, new applications that require review by one of the IRBs are not approved the first time around. The Board usually requires changes and clarifications that need to come back to the Board for review. You may assume that your new application will go to the Board at least twice: once at the initial review, when the application is tabled, and once when the PI response to the tabled letter is reviewed. However, it is quite common for a second round of letters between the IRB and the PI to be exchanged.

This process is more efficient when the primary reviewer, who is responsible for presenting the new application to the Board, is able to contact the PI of the study in advance of the IRB meeting. The primary reviewer is often able to identify issues that a PI may address by phone or email in advance of the meeting, and this exchange helps to move things along more quickly.

Both IRB-X and IRB-FC meet weekly to review new applications; IRB-FC on Wednesdays, IRB-X on Thursdays. If a PI submits a new application in PHIRST on a Thursday by 3pm, it will be assigned to a research subject specialist. The specialist will review the application for completion, and when all the parts are in place, the study will be assigned a primary reviewer. If the application is complete, if it is an IRB X study, the application will go on the next Thursday’s IRB-X meeting agenda; if it is an IRB-FC study, it will go on the meeting agenda for the Wednesday 13 days after submission.
Letters after each meeting go out to PIs by the Monday following the IRB meeting. So, the turnaround time from that point on depends on how quickly the PI responds to the IRB’s letters. PI responses are put on agendas up until a day or two before the meeting, unless there is some complication associated with the response.

This schedule does not apply to studies being reviewed as not research, not human subjects research, or exempt by the Exempt team. These applications do not require Board review and are typically, but not always, processed faster.

29. How long does it take to receive my approval notice and approved documents once my submission is approved?

Once a submission has been approved, the research subjects specialist will forward the materials to the appropriate research subjects coordinator to prepare the approval notice and approved documents. The turnaround time for when you receive your approval notice and approved documents depends on the workload of the coordinators. If you need your documents within a certain timeframe, please be sure to communicate this with the specialist in advance, so he/she can work with the coordinator to accommodate your request. Otherwise, approval documents for submissions are processed as received.

When to Submit

30. Do I need IRB approval?

If you are a faculty investigator, it depends on what your study will involve. Please refer to the guidance on “What needs review by the IRB.” If in doubt, please submit a new application or contact us.

If you are a student, the answer is always yes. All student projects require IRB review.

31. I am serving as a consultant on a research study at Institution X. Do I need to submit to the JHSPH IRB too?

Please review our guidance on “When is an Institution or PI ‘Engaged’ in Human Subjects Research.”