

Just-In-Time Submissions vis a vis the IRB

What the Just-In-Time Procedure Is

NIH uses “Just-In-Time” (JIT) procedures for certain programs and award mechanisms. These procedures call for limited information (e.g., a budget justification and a biographical sketch) to be submitted with investigator-initiated applications and allow for a possible NIH request for additional information, including information concerning other support, when the application is under consideration for funding. *Just-in-time procedures also allow an applicant to defer certification of IRB approval of the project’s proposed use of human subjects, verification of IACUC approval of the project’s proposed use of live vertebrate animals, and evidence of compliance with the education in the protection of human research participants requirement until after completion of the peer review and just prior to funding.* (Applications in response to RFAs also may be subject to these procedures. The RFA will specify the timing and nature of required submissions.) Additional information about JIT procedures can be found at http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm

Step 1: Verify it’s JIT

First verify with the Grants and Contracts Office (GCO) that your grant proposal meets the criteria for the NIH’s Just-in-Time procedures. If it doesn’t meet the criteria, you will need to submit all your required paperwork at the time of submission to the GCO. At the current time, JIT processing only applies to specific NIH grants. All other grants should be accompanied by your IRB submission

Step 2: Submit to GCO

If your grant meets the criteria for the NIH’s Just-In-Time procedures, you may submit your grant application to the GCO for institutional sign-off without including your IRB paperwork. No copies of your submission should be brought to the IRB at this time. Mail your application to the NIH without delay.

Step 3: Score

If you receive a score in the approximately fundable range, start preparing your IRB paperwork (if you haven’t already done so) **IMMEDIATELY**. If you need to know what forms to fill out, consult the IRB website checklists first, then call the IRB if you have further questions. Since it takes a minimum of 5 weeks for full-board projects to go through one IRB cycle, please **DO NOT DELAY** in submitting to the IRB.

Step 4: Submit to IRB

Once you’ve filled out the IRB forms that are applicable to your project, assemble the “full application packet” by collating your newly completed IRB forms with a copy of the completed GCO forms you previously submitted, as well as your grant application and/or a “working protocol”. A “working protocol” is an abstraction from your grant application of the elements of a standard protocol (see “New Project Checklist” on our website at http://www.mssm.edu/irb/app_info/checklists.shtml). This document prepared by you (often a simple Microsoft “Word” document) can be modified during the grant period as needed (as opposed to the original grant application itself); it should therefore contain a version number and date in its footer. Place a memo on top of the full application that states the GCO number of the project, that this is a “Just-In-Time” submission, and that you received a good score and wish the project to be reviewed now.

Please bring the application to be logged in **at the IRB office**. You do NOT need to go to the GCO office. You will simply need to say to the IRB team member, “This is a Just-in-Time submission. We received a good score and are submitting this project for review now.” There is a special inbox for Just-in-Time submissions; make sure your submission is placed in that box. Bring in your submission as soon as possible so that the IRB can review it as soon as possible. If you have *delayed* in submitting your JIT submission to the IRB and your program officer is now demanding your IRB approval immediately, please call the IRB to help you in managing your situation. But please do not get in this situation by following Step 3.

Step 5: Check with the IRB

If you haven’t heard from the IRB within 2 weeks of the date you submitted to the Just-in-Time inbox, follow-up with a phone call. You may have submitted your paperwork right before an IRB meeting and are waiting for your project to be reviewed at the next scheduled meeting.

Step 6: Respond Promptly

Once you’ve received feedback from the IRB, pay attention to the submission schedule deadlines on the IRB website so that you experience no unnecessary delays. Contact the IRB if you have any questions.

Step 7: Preliminary IRB approval Pending Funding

Once you have addressed all issues and concerns, you will receive 2 documents indicating that your NIH project has been IRB approved PENDING RECEIPT OF FUNDING. A copy of the signed document should be sent in to the NIH. You may not begin working on the project until step 8 has been completed.

Step 8: Receipt of Notice of Award

When you receive your Notice of Award, compose a memorandum that indicates that you’ve received your notice of funding in the Revisions inbox, and also indicates whether you are aware of any information (e.g. a new risk, new procedure) that would require a modification to your protocol and/or consent form (if applicable) at the current time.

If no modifications are necessary, indicate so on the memorandum and submit it to the Revisions inbox at the IRB. You will shortly receive final IRB approval documents, including “stamped” consent forms that will allow you to commence work on your research.

If you are aware of information that necessitates a revision to your project, immediately submit all of the relevant documents regarding the revision (see the IRB checklist for Revisions http://www.mssm.edu/irb/app_info/checklists.shtml), along with the cover memorandum mentioned above, to the Revisions inbox at the IRB. The revisions will be reviewed and, upon approval, final IRB approval documents will be provided to you that will allow you to start your work on the project.

Step 9: Begin Your Research

Once you are in possession of your final IRB approval documents, you may begin your research activity.