



## SEVEN STEPS

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**I have a step-wise process that I use to help investigators approach the NIH for the first time...so far it is working pretty well. I invented it over the last five years, so it really isn't validated yet! To START: please read ALL SEVEN STEPS through, before you DO anything!**

**WARNING: There are never any guarantees in the funding world, private or public. But, getting all the way through these steps, and generating an application will be a rewarding process in and of itself, and many have found the process and product rewarding. (\*\*\*)One thing that I have noticed is, that people my own age (55 at the time these were written) find it very hard to DO THE STEPS. So, I am looking for a volunteer to help me write a version for the more seasoned in seeking support: IF YOU ARE INTERESTED IN DOING THAT, PLEASE WRITE TO ME at [nicholca@mail.nih.gov](mailto:nicholca@mail.nih.gov) (\*\*\*)**

## **Step I: Your Notebook**

Get a BIG Notebook with dividers.

Quietly peruse all the material at:

[http://grants.nih.gov/grants/grant\\_basics.htm](http://grants.nih.gov/grants/grant_basics.htm)

[http://grants.nih.gov/grants/grants\\_process.htm](http://grants.nih.gov/grants/grants_process.htm) until you feel ready to print out what you will need for your notebook. This will take an hour or so.

And, I think it is helpful to have a hardcopy of these forms in your Notebook so that you can flip through it when you are preparing your esubmission. So, go there, and add that now to your notebook, unless you are able to do without it.:

<http://grants.nih.gov/grants/forms.htm>

A. Download Forms and Instructions and make a Notebook with table of contents and Dividers....some people find that their funding mechanism or opportunity is NOT going to have esubmission....and so, they need to use paper!

So, here is the link to clarify that....go there!!!

<http://era.nih.gov/ElectronicReceipt/>

And, for the old 398, if you or your mentor are used to that, and need to orient yourself.

<ftp://ftp.grants.nih.gov/forms/phs398.pdf>

In either case, You will need ALL the pages handy, and the table of contents...I also think it is useful to keep a blank PHS form in the front pocket of the notebook, and to download the FAQs as well and keep them there. Then, if you are applying to a specific RFA or PA from the NIH Guide, When you have questions that you need to ask someone besides me, you can call the grants info staff at 301-435-0714 or email them at GrantsInfo@nih.gov. They are very friendly, and when you have questions about electronic submission, mailing, labels, copies, FEDEX, etc....they are always there to help. Of course, we really love to hear from the investigators as well!

B. When you get to steps 4 and 5, below, it is helpful to keep handy the material at

[http://sciencecareers.sciencemag.org/career\\_development/previous\\_issues/articles/2006\\_11\\_10/nih\\_s\\_center\\_for\\_scientific\\_review/](http://sciencecareers.sciencemag.org/career_development/previous_issues/articles/2006_11_10/nih_s_center_for_scientific_review/)

. So think about checking this out in the early stages, so you know what is there; you are writing for an audience of reviewers. Try to take their point of view by cruising the NIH CSR website, looking at the instructions given to reviewers.

C. You can read the instructions to reviewers, and I really recommend doing this ahead of time. This is how the reviewers are told by NIH to review your application. Your scientific priority score will be assigned using these guidelines. The instructions for reviewers can be accessed at :

<http://www.csr.nih.gov/guidelines/guidelines.htm>

I think it will be very helpful for you to spend some time cruising through the CSR ( Center for Scientific Review) website ( checkout <http://www.csr.nih.gov/Committees/rosterindex.asp#A> )before you go any further. You can see the roster and content area of many study sections. If you are responding to an RFA, you need to realize, that a special, one-time only study section will be convened to review the RFA applications, and the roster won't be on the site....BUT the guidelines for the review of the funding mechanism specified in the RFA are....and the RFA itself will be very specific about the review criteria!

**\*\*\*Before you start, though, let me review your step #2 "three things"...\*\*\* (so, don't plunge in yet!) So, this may be the time that you contact the NIH program staff...**

**D. Identify NIH program staff who will advise you. If not sure, contact me and I will help you find someone. If you and/or your research, do not fit into my program, we will find an NIH home together for your proposal.**

**Do not worry about that, please, at this stage. YOU are the investigator, and it is your scientific vision you are sending to the NIH....so, YOU will get to choose where it is submitted! But, you need help, no matter where you are submitting it, OK? Or if you are so experienced and successful that you do NOT need help, you do not need to do the SEVEN STEPS!**

**E. Make a timeline for the following six steps, working backward from your identified due date. Look at the NIH review cycles in your notebook/online, and think about what will work with your onservice time, etc. Your timeline should be written, realistic and generous.**

**F. So, that is it for today!**

**I really suggest that you review your notebook, and think about your three things (see below) a little. Now, take a day to think about your commitment to research, and the NIH process. Promise yourself that it is your research career, and you will stay connected with YOUR vision, to make things BETTER !!!Let me know if you need more help with this very important FIRST step!**



## **Step II: Getting you and your science ready for peer review**

A. Email the three things you would accomplish for medicine, science and children with critical illnesses and/or disabilities to your me or your identified program staff.

B. These three things will be criticized and tightened up, hypotheses and null hypotheses suggested where appropriate, and emailed back to you . The programmatic appropriateness of these three research aims will be evaluated. At this stage, you may be directed to another NIH IC or Program Director....wherever you will have the best chance is where you need to be!

## **Step III: Look at the scientific mandates of the work you propose:**

Remember, the SCIENCE has to be startling, clear, and compelling. So, no amateur hour analytic plans for your findings, ok?

A. Obtain formal professional biostatistical help, giving the biostatistician the research aims. Ask for a power analysis, and a synopsis of the biostatistical modelling/analysis which will be used. Make sure you understand the concepts well, so that it is easier to formulate a research plan. Remember to take notes as the biostat professional speaks, look them up in your biostat book, so it stays inside your mind as you write. It helped me to find an example of work unrelated to mine, but similar in statistical analysis approach and read it.

B. Read and reread the world's literature, especially paying attention to studies similar to yours, and search CRISP, the public database of NIH funded projects, available at:

[http://crisp.cit.nih.gov/crisp/crisp\\_query.generate\\_screen](http://crisp.cit.nih.gov/crisp/crisp_query.generate_screen) . Crisp can be tricky to use, so give yourself a couple of hours JUST TO LOOK at Crisp. And, of course PUBMED. How is your work/ approach to this problem different than that already being done?

## **Step IV: Making a Grant Proposal**

A. Make a very detailed ( what species of rats or pigs, what reagents, how many human subjects over what period of time, exclusion,

inclusion criteria, what medical centers, which pathologist and why...etc, etc, ) outline of your research plan; This usually takes about four weeks.

- B. Give the above programmatically critiqued “ three things”, power analysis, and detailed outline to an R01, or roadmap- funded researcher at your institution who is NOT POLITICALLY CONNECTED to you in any way. Ask for a harsh criticism, and ask them for any suggestions. Give them a full three weeks to do it. \*\*\*\*The reason for this is that it is likely that although all of the reviewers in the study group who evaluate and score your work will be accomplished scientists, many will not be in your field. \*\*\*\***

*You would be surprised how many things that are patently apparent to a person from one discipline , are obscure to those from another. I believe that your ability to make your case in this very competitive peer-reviewed arena will be enhanced by going to the SCIENCE magazine website( <http://www.sciencemag.org/> ), and reviewing the work of a beetle doctor, anthropologist or astronomer. Besides, if you click on **NEXT WAVE**, a whole world of help with grant writing and funding will be opened to you. They have a **Grant Doctor**, and a **Funding Search Engine**, to match you with private supporters of research. And, they have the **R01 toolkit** mentioned above.*

- C. While IVB is being done, get the IRB OR IACUC forms together on your desk, and line up letters of support, and start writing the Introduction, Aims, Background, Significance and Research plan, following the directions in your notebook very carefully. PAGE limits are STRICT at the NIH.... Call program staff for any clarifications or questions. I really think that at this stage you are best served by listening to us....we want to help!**

- D. As you begin to write, keep in mind the purpose of the published RFA or PA (if any), and the NIH evaluation/scoring criteria, which you should have memorized by now.**

**If it is possible for you to take a writing class at your university....just a part time one.....it would help! Especially the kind where you learn to convey vision, tension, conflict and solutions succinctly, and rapidly. If they offer a beginning screenwriting class, that would be ok, short stories, poetry, whatever would help you learn to communicate your vision to others. You might think this is not**

necessary, but several of my R01 successful applicants who reluctantly did it were amazed at how much it helps!

## V. An NIH Application Emerges

A. When the critiqued outline is available, back from the R01 researcher (don't forget a thank you note), make a grant out of it. Complete a draft of the entire proposal, including the budget. Most budgets these days are modular, and this should save you some aggravation. You should allow *eight full time weeks* for this transition. And, the idea is, even if it gets revised after this, **YOU HAVE A DRAFT...**you can ask the scientist who helped you in step 2 to take a look at it, and your colleagues, too... At the end of this time, your proposal should look like a grant. Follow the instructions in your notebook carefully,\*\*\* adhere to page limits.\*\*\* **PUT IT AWAY.**

B. After at least a five day break, look at the grant again, and tune and tweak. Get your institutional and departmental signoffs.

C. Chip away at your IRB submission, so that it is ready to turn in the week before your peer review(or sooner). You do NOT have to have IRB approval before you send in the grant, but they will not release the funds to you until you have this.

### Step VI: Get it to the NIH, and get the Institute, Program and Review Assignments that seem right to YOU!

A. Compose the cover letter. In my own opinion, It is very important to contact program staff for editing assistance with this...probably you will back and forth it a couple of times. You will use it to request for consideration of funding , and study group assignment for review. **FUNDING AND REVIEW ARE SEPARATE.** This still seems to confuse everyone...

A. FEDEX paper submissions ( overnight)to the NIH.... 10 days before the due date.

5 days later, make sure it is here.

Contact information for receipt and referral: 301-435-0714 or email them at GrantsInfo@nih.gov.

C. Put it in a drawer for a while, but keep attending to the world literature and to CRISP

D. Find out who the SRA is for your review, and the study section assignment. You will use your eRA commons account for that.

E. After review, it is important for you to go over your summary statement in detail with program staff, who will also be able to give you guidance re: likelihood of funding at this point, or after resubmission. If you have to do rewrites, wait until you have read and digested the summary statement. Ask the R01 level researcher to review the summary statement with you as well.

VII.REST, don't quit, REST, don't quit!



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**\*\* If sending FEDEX replace last line with Rockville, MD 20852**