



eCGAP Focus Group

Date: Thursday, May 26, 2005
Time: 2:15 p.m. to 4 p.m.
Location: Rockledge 1, Room 8111
Advocate: Jennifer Flach

Next Meeting: Tuesday, June 7, 9:45 a.m. to 11 a.m., Rockledge 1, Room 2198

Action items

1. (Jennifer Flach) Inform Service Providers that the Inclusion Enrollment Report should be placed in Section E.
2. (Sara Silver) Update requirements to change the wording of bookmark to state: “Inclusion Enrollment Report and/or Targeted Enrollment Table” and schedule the change in time for the October 1 receipt date.
3. (Suzanne Fisher) Add this note to printed copies of eCGAP applications sent to reviewers: “If there is an Inclusion Enrollment Report, it will be found with the Targeted Planned Enrollment Report due to the way the data is structured.”
4. (Manju Subramanya) Inform Service Providers that for applications that come in with no human subjects, Service Providers should include a Protection of Human Subjects attachment, containing the title “Section E. Human Subjects Research,” followed by “No human subjects research.”
5. (Sara Silver) Compile number of eCGAP applications received to date that involved human subjects and send to group.
6. (Manju Subramanya) Send out Commons Working Group meeting slides with these minutes.
7. (Sara Silver) Craft sample subject lines for enotification and email it to the group for feedback.
8. (Sara Silver) Incorporate appendix discussion items in future requirements.
9. (Tom Tatham) Recommend to Scarlett Gibb that the following sentence be added to the Submitting Grants Electronically webpage (http://era.nih.gov/Projectmgmt/SBIR/sbir_grants.htm) to clarify the “select grant applications” sentence: “Applicants will be able to submit applications for those grant opportunities that are posted by NIH on the Grants.gov website as packages for Apply.”
10. (Jennifer Flach) Inform Service Providers that the certification chart will be posted on a specified date and they have to complete their recertification by that date.

Discussion of new 398 issues

Sara Silver and Michael Goodman

Inclusion Enrollment Report—Mike Goodman noted that the instructions for the new 398 form specify that the Targeted/Planned Enrollment Table should be in the Human Subjects Section (Section E) of the Research Plan. A Service Provider asked where the “Inclusion Enrollment

Report” should be presented. The eCGAP Team’s initial response was to inform the Service Provider to place the Inclusion Enrollment Report in the Section C Progress Report. But the Service Provider thought it would count against the 25 page limit on Sections A-D and should be placed in Section E. Mike wondered if the focus group could provide some guidance. Suzanne Fisher stated that the Inclusion Enrollment Report clearly belongs in Section E. She also noted that the Inclusion Enrollment Report never counts against the 25 page limit in Sections A-D.

Mike noted that the Service Provider had a follow-up question:

Q. When submitting an application for continuation, is it feasible for the applicant to submit an Inclusion Enrollment Report but no Targeted/Planned Enrollment table?

A. Suzanne noted that yes, an applicant could be done enrolling subjects but needs more time to analyze the data.

In that case, NIH may receive applications that have a Table of Contents entry saying, “Targeted/Planned Enrollment Table,” when in fact that information in that page presents only the “Inclusion Enrollment Report.” Suzanne asked if it was possible to change the wording of the bookmark to say, “Inclusion Enrollment Report and/or Targeted Enrollment Table.” Sara noted it was too late to make that change for June/July, but that it is possible for the October/November receipt dates.

In the interim, Suzanne said she would alert reviewers by adding this note to the printed copies of the eCGAP applications sent to reviewers: “If there is an Inclusion Enrollment Report, it will be found with the Targeted/Planned Enrollment Table due to the way the data is structured.”

Sara asked if the Table of Contents entry needs to be changed. Mike said that the issue should be tabled since it may involve policy.

Jennifer noted that while the Targeted/Planned Enrollment table comes in currently as a PDF, it will eventually come in as structured data and this issue will be moot.

Action: (Jennifer Flach) Inform Service Providers that the Inclusion Enrollment Report should be placed in Section E.

Action: (Sara Silver) Update requirements to change the wording of bookmark to state: “Inclusion Enrollment Report and/or Targeted Enrollment Table” and schedule the change in time for the October 1 receipt date.

Action: (Suzanne Fisher) Add this note to printed copies of eCGAP applications sent to reviewers: “If there is an Inclusion Enrollment Report, it will be found with the Targeted Planned Enrollment Report due to the way the data is structured.”

Handling Human Subjects— Sara noted that the instructions for the new 398 specify that all applications are supposed to have a human subjects page that says “No human subjects” if there are no human subjects. Due to an oversight, that functionality was not included for eCGAP applications.

Sara suggested that, as a workaround for applications without human subjects, Service Providers include a Protection of Human Subjects attachment, containing the title “Section E. Human Subjects Research,” followed by “No human subjects research.” The group agreed that was a good idea for the short-term. Suzanne suggested it would be good to fix the problem for the July 1 receipt date. Sara said it would involve a schema change and they would look into it. Suzanne also asked how many CGAP applications involved human subjects. Sara said she would compile the numbers and inform the group.

Action: (Manju Subramanya) Inform the Service Providers that for applications that come in with no human subjects, Service Providers should include a Protection of Human Subjects attachment, containing the title “Section E. Human Subjects Research,” followed by “No human subjects research.”

Update: The above suggestion did not work as planned because the software inadvertently prevented eCGAP from generating an image of the attachment submitted.

Action: (Sara Silver) Compile number of eCGAP applications received to date that involved human subjects and send to group

Requiring Entry of Subtotals on Modular Budget Page— Sara noted that the instructions to the 398 form state that if the applicant has no consortium Facilities & Administrative costs (F & A costs), he or she should enter only the total cost on the Total Direct Costs row on the modular budget page. However, because the schema does not allow for missing values on the top line, an eCGAP applicant must enter costs on the DC less Consortium F&A row *and* on the Total Direct Costs row, even if there are no Consortium F&A costs. A Service Provider expressed concern that this was not in line with the 398 instructions. The eCGAP team has instructed Service Providers to enter costs on the top and bottom rows (and on the Consortium F&A line if applicable), and has ensured them that NIH will validate that the numbers add up correctly. The group noted that that solution is acceptable and fine by Review.

Update on Commons Working Group meeting

Jennifer Flach

The Commons Working Group meeting was held on Sunday, May 22, in Washington D.C. Jennifer noted that the CWG had some concerns about having mixed forms in review. They discussed the 424RR; other than that, there is not much to report.

Suzanne suggested that the CWG meeting slides be sent out to the group with these minutes.

Action: (Manju Subramanya) Send out Commons Working Group meeting slides with these minutes.

Update on Grants.gov testing

Jennifer Flach

Jennifer noted that the NIH-Grants.gov acceptance testing exercise with four members of the Commons Working Group went well. The exercise gave the testers an opportunity to fill out the 424RR and agency specific forms. An application was successfully submitted to Grants.gov. The testers in turn gave the eRA team feedback on applicant instructions. The exercise will help eRA better educate the applicant to make the entire process of submission and validation smoother for them. The CWG members also felt the exercise was worthwhile for them.

Jennifer noted that eRA had lost one of its valuable developers and therefore was behind schedule with development. As a result, eRA had not been able to conduct the second part of the acceptance testing, namely viewing the submitted 424RR and NIH specific application in Commons, validating the application for errors or warnings and having the applicant verify the application.

Jennifer said that she is considering a follow-up exercise, either by setting up another session or conducting the exercise remotely through web casting. Tom Tatham suggested that they could use the services of Premiere Reservations, which provides web casting services.

Review Action Items from May 3 meeting

1. (Sara Silver) Find out if ICs can designate a person and a back-up who will receive email notifications after applications have been assigned to an IC, instead of having the email go to both DEAS staff and SRAs. ***Yes, ICs can designate a person and a back-up using an email address or role. In addition, this ability can be set up in enotification, which is currently in production. An IRG chief will be able to log in and see a queue of all applications assigned to him or her.***
2. (Sara Silver) Craft sample subject lines for enotification and email it to the group for feedback. ***This item is not yet done. Sara will send it out soon.***
3. (Suzanne Fisher) Add a line in the memo that accompanies printed paper applications to reviewers, urging them to check the grant folder for appendices. ***Done.***
4. (Sara Silver) Suggest to Tracy Soto and Daniel Fox that they include a link to the appendices in the Internet Assisted Review module. ***After much discussion between the parties involved, it was decided that this feature is not going to be implemented at this time for various reasons.***

Discussion: Suzanne noted that this issue will have to be revisited sometime because the Scientific Review Administrator needs some way to separate appendices that come in to eCGAP in a big bundle right now. This ability is needed to separate allowable sections of the appendices from sections that are nonconforming if applicants have bundled them together inappropriately.

Tom noted that if an appendix comes in with an application at the time of submission and the SRA rejects it, there should be an indication that a document was submitted but not permitted. This is needed for the reviewer who may see appendix c listed in the application, but not see an actual appendix c because it has been disallowed by the SRA. In addition, Tom stated that he sends a courtesy email to the PI stating that an appendix has been removed because of nonconformance. Sara asked if an enotification to the PI would be useful at this stage; the group agreed it would be. The group also agreed that the SRA needs the ability to allow/disallow an appendix attachment later in the process as well. An appendix attachment that is “disallowed” should not be displayed as part of the grant folder.

JJ Maurer asked if it would be helpful to have snapshots or copies of application images stored at key decision points. The group agreed it might be helpful to store these images up until a month after the Council round.

Sara noted that Grants.gov allows submission of multiple appendices. The ability to handle multiple appendices was also listed as a to-do item for eCGAP, but has not been funded.

(Sara Silver) Incorporate appendix discussion items in future requirements.

Table Talk

Submitting Grants Electronically webpage—Tom Tatham said that eRA’s Submitting Grants Electronically webpage (http://era.nih.gov/Projectmgmt/SBIR/sbir_grants.htm) includes a sentence that states, “We hope to have that interface in place by Fall 2005 to accept select grant applications via Grants.gov.” He expressed concern that an applicant may skim over the word “select” and have a broader expectation of the types of NIH grants that will be available via Grants.gov. He suggested that the word “select” be defined so as not to confuse potential applicants. Jennifer stated that while eRA is proactive about promoting submissions through Grants.gov, they need to be careful about defining the types of grants in advance. Sara suggested adding verbiage to say, “Applicants will be able to submit applications for those grant opportunities that are posted by NIH on the Grants.gov website as packages for Apply.” The group agreed with the wording and suggested Tom convey that to Scarlett Gibb.

Action: (Tom Tatham) Recommend to Scarlett Gibb that the following sentence be added to the Submitting Grants Electronically webpage (http://era.nih.gov/Projectmgmt/SBIR/sbir_grants.htm) to clarify the “select grant applications” sentence: “Applicants will be able to submit applications for those grant opportunities that are posted by NIH on the Grants.gov website as packages for Apply.”

Certification chart for Service Providers—Suzanne expressed concern that when she checked the Submitting Grants Electronically webpage (http://era.nih.gov/Projectmgmt/SBIR/sbir_grants.htm) on May 6, the chart listing Service Providers certified to submit applications on behalf of applicants to NIH listed only one of six Service Providers as certified. She noted that may be discouraging to applicants looking to submit electronically. Manju explained that each Service Provider has to be recertified every time there is a major eCGAP software release and they are listed one by one as certified as they complete their recertification. All of them are usually certified before the receipt date. Responding to Suzanne’s concerns, two paragraphs explaining the recertification process have been added above the chart. JJ Maurer suggested that instead of listing them one by one as certified, the Service Providers be informed that the certification table will be posted on a certain date and they need to be recertified before that date. The group agreed it was a good idea.

Action: (Jennifer Flach) Inform Service Providers that the certification chart will be posted on a specified date and they have to complete their recertification by that date.

Attendees

Fisher, Suzanne (CSR)	Maurer, JJ (OD)	Subramanya, Manju (LTS/OD)
Flach, Jennifer (OER)	Moyer, George (Skip)(AHRQ)	Tatham, Tom (CSR)
Goodman, Michael (OD)	Silver, Sara (OER)	Wehrle, Janna (NIGMS)
Liberman, Ellen (NEI)		