Pink Sheets Do's and Don'ts

Judith DeCarteret

Boston University ADC

Comment:

"…the membership and functions of these committees are clearly described. However, it would be helpful to provide more data speaking to their effectiveness."

Solution:

Identify improvements or changes made based upon committee (External Advisory etc) recommendations, describe specific actions taken in response to these recommendations.

Comment:

A concern of the previous review was the lack of clear demonstration of productivity of the Pilot Projects. This has been adequately addressed, with a clear list specifying publications and subsequent grants obtained by the researchers receiving Pilot Project grants from the ADRC.

Solution:

Create a table demonstrating pilot productivity. In a renewal be sure to show history of all pilots since the beginning of your Center.

The table should include: Pilot number, PI, Publication(s) and Subsequent Funding (as a result of the pilot)

Example: 16.1 - Joe Smith, PhD - Title of Publication -   R01 AG

Comment:

1) PIs first year budget for Administrative Core, left out justification for Pilot Projects.

2) The budget is large and largely for salaries. It is not entirely clear what everyone is doing!

3) The PI proposes to spend only 5% time on core activities. The core might benefit from more of his time.

4) Effort judged too little for core leadership

Solution:

Justify! Don't forget the Pilots in the overall budget justification.

Comment:

"The clinical cohort is carefully chosen to support the ADRC projects, but are these enough to support the large number of clinical projects conducted at the ADRC without incurring too much patient burden."

Solution:

This Center addressed the issue of participant retention and recruitment within the justification it may have been overlooked by reviewers. Address this issue within the research plan of the core.

Comment:

"Given the large number of clinical projects, there is a potential concern that the enrolled subjects may be insufficient to support all of the planned projects or may be called upon to join too many projects."

Solution:

Explain any participant tracking system that you may have to monitor the participant burden.

Comment:

Database design is sensible as are network and database security procedures. Limited description is given to backup, safe storage and HIPAA procedures.

Solution:

Be sure to include all procedures in your renewal, the reviewer will not know the basic operations and safeguards at your particular site.

Comment:

Detail as to how brains are processed in the Neuropathology Core is lacking.

Solution:

Again, be sure to include all basic procedures in your renewal.

Comment:

Application states XXXXXXXXXX, whose position was funded by a gift to the ADRC, is available for statistical consultation. Difficult to assess the value of this service with so little information about Dr. XXXXXX in the application.

Solution:

Include the position in your application, on the budget page and justification and include biosketch if applicable.   Mark the position with an asterisk on the budget page and clarify in the justification that this position is funded in part through a gift, supplement etc...

Comment:

1) The last review noted that the postmortem time was rather long and that no strategies to shorten it were provided. This does not appear to have been addressed and the average postmortem time (15.1 hrs.) in the present application is slightly longer than the average of 14.5 hrs. in the last application.

Solution:

Make sure that you address all issues mentioned in the previous Summary Statement (Pink Sheets).

Comment:

This reviewer was very upset about the lack of tables demonstrating productivity associated with tissue shared from the Neuropath Core.

Solution:

Tables give access to information quickly. Include tables for clarity whenever possible. If a table relates to more than one core, the same table should be included in each relevant core. In many cases a reviewer does not have access to the entire application and referring to another core or section of the application will result in the reviewer not having access to that information.

Comment:

Productivity of tissue distribution is difficult to determine. There are no lists of tissue distributed or resultant publications in the NP cores application.

Solution:

Show productivity of core, show tables for tissue distribution and be sure to list publications. Any publications using resources from multiple cores should be listed at the end of each core. Also include a master list in the overview.

Comment:

No power calculations or even a discussion about why this number of subjects is needed.

Solution:

Include a section on sample size that either includes the power calculations or has a very good explanation why it does not.

Comment:

- Lack of information on how various sites integrate.
- Reliability exercises between clinical sites are not described
- There appears to be limited contact between EITC and local Alzheimer's Association

Solution:

Include in your application; frequency of core and site meetings, retreats and conferences. Explain any inter-rater reliability and each core should explain their interaction with the other cores.

Comment:

"The number of control brains and (those) from minorities, continues to be problematic . . . brain bank continues to have very few specimens representing early AD, normal aging and MCI."

The main criticism of the neuropath core was that there were not sufficient non-Caucasian deaths.

Solution:

Note the problem within your application and explain a strategy to address these issues. Although these issues at some point are not in your control. Any suggestions?

In Summary

- Justify
- Explain even the basic procedures of the core
- Explain relationships and collaborations ie Alzheimer Association
- Show interactions between cores
- Use tables and include in all relevant cores
- Address all issues from the summary statement of your last submission
- Don't reinvent the wheel – take advantage of the vast experience of our group of administrators – we are all willing to share templates of tables and forms, etc.