NIH eSubmission Items of Interest - July 31, 2018

Happy National Mutt Day! Yep, it’s a real thing. And, why shouldn’t it be? I vividly remember bringing my mutt home from a pet adoption event years ago and introducing her to her new “daddy.” “She’s two dogs long and one dog tall and looks like she’s made from spare parts,” Jeff said. All true. An emaciated basset-beagle-ish dog with ears longer than her bowed-little-legs isn’t going to win any beauty contests. But, our Dixie is the most lovable hound on the planet and we wouldn’t trade her for the world.

Mutts are amazing, but what do they have to do with grant application submission? Not much actually, but if you love your mutt as much as I love mine, then I’ve at least got your attention. Besides, who passes up the opportunity to celebrate? More wag, less bark!

Hopefully you’ll find this edition to have an interesting mix ... not unlike your favorite mutt.

Where Do I Put the Information I Know You’d Want, But Didn’t Ask For?

You want to give staff and reviewers ALL the information you think they need to provide a thorough review of your proposal. There is certainly nothing wrong with that - right? Well, actually it depends. The application guide and funding opportunity announcement provide very specific guidance on what to include in your application and, in some cases, there are page limits you must stay within to convey the requested information.

If you have information that doesn’t fit in page-limited attachments like your Specific Aims and Research Strategy, rework those attachments until you tell the best story possible within the confines of the page limits. Do not try to stuff that extra information into other non-limited fields of the application forms. Similarly, if you have information that doesn’t have a “natural home” based on our instructions, don’t include it.

There are several form fields with tempting names like “Appendix,” “Other Attachments,” “Other Requested Information,” and “Other Clinical Trial-related Attachments.” DO NOT use those fields unless requested to do so in the application guide or announcement.

Why not? Even if you have the best of intentions, you need to resist the temptation to force fit information into your application where it doesn’t belong. The page limits and guidance are there for fairness and you may find your application pulled from consideration if you try to get around them (NOT-OD-11-080).

The Duplication Balancing Act

The application guide statement “do not duplicate information between the Research Strategy attachment and the PHS Human Subjects and Clinical Trials Information form” appears to be causing some angst in the community. In fact, our new human subjects form invites a certain amount of overlap between the sections. It would be difficult, for example, to provide a “Brief Summary” of a protocol without talking about information captured elsewhere in the application.

The point we were actually trying to make is that we don’t want you to copy and paste blocks of text into multiple places in your application. Your Specific Aims and Research Strategy should include enough human subjects and clinical trial information to tell a cohesive and complete story. The human subjects form is meant to provide structured, supporting details for the study (sorry, it isn’t just extra space to expound on the research strategy). The Brief Summary in the Protocol Synopsys section of the human subjects form aligns with what the public would see in ClinicalTrials.gov without the benefit of the full application. It should hit the key points at a very high level in as close to plain language as possible.
The bottom line is there will be some overlap of information within your application, but reviewers should not be reading blocks of text copied verbatim into multiple sections of the application.

**Space-Fill Compulsion**

My mother, an interior designer, never saw a horizontal surface she didn’t want to decorate. For years I encouraged her to declutter and often she’d begrudgingly remove a knick-knack from a table of shelf. But the next time I’d visit a new knick-knack was sitting right it its place. My dad calls it space-fill compulsion.

Our new human subjects form has several text fields with large character limits (e.g., Eligibility Criteria - 15,000 characters; Brief Summary - 5,000 characters; Narrative Study Description - 32,000 characters). These character limits match those in ClinicalTrials.gov and were set artificially high so the system could accommodate more characters than are actually needed.

Here is a fun little tidbit we’ve learned ... folks who are already funded and entering information into ClinicalTrials.gov tend to be more pithy than folks applying for funding. Could it be that while composing your response you see the character count is well below the available space and assume NIH wants more? Space-fill compulsion, perhaps?

If you’ve covered what you need to say in a few paragraphs, then stop. You don’t need to fill the entire allotted space. Eligibility criteria is typically quite succinct. A Brief Summary typically runs 2,000 characters or less and the Project Narrative typically 5,000 characters or less. It would be unusual to come even close to the character limits for those fields. It’s, OK. Cover the topics using only the space you need.

Remember, this is the supporting detail for your story, not the story itself. Less is more. Don’t bury your main point under unnecessary information.

**Do Fellowship Awards Allow Clinical Trials?**

We encourage fellows to receive training in clinical research, including clinical trials. NIH-supported fellows just can’t independently lead them. The career stage of a fellow may not yet align with the responsibilities of navigating all the components, complexities and reporting requirements associated with a clinical trial. In addition, fellowship grants do not include sufficient research funds to support the majority of clinical trials. Consequently, all Fellowship opportunities are posted as independent Clinical Trials Not Allowed.

The sponsor is the responsible individual of record for oversight of the trial. He or she is ultimately responsible for tasks like interacting with relevant Institutional Review Board (IRB) staff, reviewing all informed consent documents, reporting potential serious adverse events, and maintaining responsibility for patient safety. But there are no restrictions on the responsibilities the fellow can assume with the sponsor’s oversight.

If you plan on submitting a fellowship application, clearly delineate the roles both the sponsor and the fellow are undertaking. This can be done in the Sponsor and Co-Sponsor attachment for the sponsor and the Research Strategy for the fellow. It needs to be clear that the fellow is not the responsible individual. Overselling their role to the point where it looks like they are leading the trial can hurt more than it helps. It’s fine to show the fellow working side-by-side with his or her sponsor through every aspect of the trial. It’s not OK for them to be off on their own shoulderling all the responsibility themselves.
Dog Days of Summer

“Be the person your dog thinks you are.”
~ George Eliot aka Mary Ann Evans

Stay cool and if you’re lucky enough to have one, give your mutt an extra hug.

Take care,

Sheri

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