MEG BOUVIER MEDICAL WRITING

NIH INFORMED

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Insights from NIH notices and reviewer comments, so you can focus.

MAY TIP

I answered "yes" to the 4 clinical trial questions. I know I have to have a Data and Safety Monitoring Plan, but I was wondering if I need a Data and Safety Monitoring Board? The guidelines don't really say. If you need a DSMP, do you *need* a DSMB? Do the reviewers score you down if you don't have one?

Opt for a DSMP for lower risk projects and a DSMB for higher risk projects.

If you answered yes to all four clinical trial questions, then you are conducting an NIH-defined clinical trial and must complete all 5 sections of the PHS Human Subjects and Clinical Trial Information Form. Item 3.3 requires you to attach a PDF of your Data and Safety Monitoring Plan. Item 3.4 asks, "Will a Data and Safety Monitoring Board be appointed for this study?" First, check your FOA to see if it requires a DSMB, as some of them do. If not, you must make a judgment call about whether to use a board. So, how do you decide between plan versus board? As a general rule of thumb, if your trial is earlier phase or lower risk, use DSMP only. If your trial is later phase, higher risk, interventional, or multi-site, then propose a full DSMB. If you have any question in your mind at all about whether to include one, err on the side of caution and propose the DSMB.

Have a grant-related question? Submit what's on your mind and we'll answer it in a future newsletter.

MAY NEWS

1. NIH continues accepting prelim data as post-submission materials
2. Data regarding age of participants in NIH-supported clinical trials now available
3. New NIH web site on Scientific Data Sharing
4. The latest roundup of some NIH-sponsored COVID-19 research

1. NIH continues accepting prelim data as post-submission materials

NIH extended the ability to accept preliminary data as post-submission materials to applications submitted for the January 2023 council (beginning with submissions for the May 25, 2022 due date). A few conditions to note: (1) The FOA must allow preliminary data; (2) Preliminary data update is limited to 1 page for a single component application or 1 page for each component of a multi-component application; and (3) the deadline for submitting all post-submission materials, including preliminary data, will be 30 days before the study section meeting, unless specified otherwise in the FOA. The full notice is available here.

2. Data regarding age of participants in NIH-supported clinical trials now available

Data regarding age of participants in NIH-supported clinical trials is now available in addition to previously available data on participant sex or gender, race, and ethnicity. NIH instituted the Inclusion Across the Lifespan policy for grants submitted on or after January 25, 2019. Since then, studies falling under that requirement have submitted this de-identified information in progress reports. NIH encourages the use of RCDC data to justify gaps in the literature when writing your Significance section of the grant application.

To access the information, go to the RCDC Inclusion Statistics Report then click to download the Human Subjects System (HSS) Enrollments Excel file. The link is at the end of the introductory information on the link above, or download directly here.

3. New NIH web site on Scientific Data Sharing

NIH has a new website on Scientific Data Sharing. The site serves as a centralized portal to all NIH-specific policies regarding data sharing and data repositories. On the site, researchers can find information regarding data management and sharing, genomic data sharing, and other sharing policies; information on writing and budgeting data management and sharing plans; and links to NIH-supported scientific and genomic data repositories.
NIH produced a short video about the site's highlights, which can be viewed here.

4. The latest roundup of some NIH-sponsored COVID-19 research

Over the past year, the NIH has kept the scientific community abreast of COVID-19 developments via a website with a multitude of information.

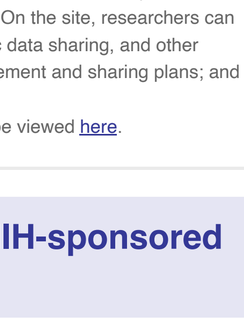
The site includes NIH's strategic priorities for COVID-19 research and the 2021 NIH-wide COVID-19 Strategic Plan. There are COVID-19 research initiatives and datasets, tools, and publications.

Here are some other COVID-19 related headlines:

- Targeting COVID-19 variants to stop infection before it begins
- Study looks for long COVID risk factors
- Understanding the range of reactions to SARS-CoV-2

Exciting News!
Our new course library platform is now live!

Margaret Bouvier received her PhD in 1995 in Biomedical Sciences from the Mount Sinai School of Medicine. After an NINDS post-doctoral fellowship, she worked as a staff writer for current NIH Director Dr. Francis Collins in the Office of Press, Policy, and Communications for the Human Genome Project and NHGRI. Since 2007, Meg has specialized in editing and advising on NIH submissions, and began offering virtual courses in 2015. She currently supports 2 of the top 3-ranked hospitals; 4 of the top 6 cancer hospitals; and 3 of the top 6-ranked medical schools for research in the country. She has helped clients land over $400 million in federal funding. Meg Bouvier Medical Writing, LLC is a woman-owned, small business.



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