Dear COGR Members,

We contacted NIH today in response to requests from numerous members for clarification as to whether NIH is requiring that institutions provide the supporting documentation specified in NIH NOT-OD-21-073 as of May 25, 2021. These questions arose after yesterday’s NIH blog post and modified FAQs on this topic.

Please see the email trail below with the question that we sent to Dr. Lauer and his answer. We are sharing this email response with permission from Dr. Lauer.

After receiving Dr. Lauer’s response, we let him know that stakeholders were confused by the wording in the blog post and amended FAQs and asked if NIH would consider posting additional clarification. We will continue to keep members informed as we receive any additional information.

Please contact Jackie Bendall (jbendall@cogr.edu) or Kris West (kwest@cogr.edu) if you have questions regarding transmittal.

Email Response from Dr. Lauer to COGR:

From: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>
Sent: Thursday, May 6, 2021 12:44 PM
To: Kristin West <KWest@cogr.edu>
Cc: Wendy Streitz <WStreitz@cogr.edu>; Robert Hardy <RHardy@COGR.edu>; Jackie Bendall <JBendall@COGR.edu>; Michael Lauer <michael.lauer@nih.gov>
Subject: Re: Clarification on Yesterday's Blog Post Re. NIH NOT-OD-21-073 and NIH OD-21-110

Hi Kristin – “b” is correct – “NIH will not require that supporting documentation be disclosed to NIH until January 25, 2022, but institutions may be asked by NIH to provide them prior to this date, if necessary.”

Yes, you can share with others.
Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: 301-496-1096
Email: Michael.Lauer@nih.gov

Email from COGR to Dr. Lauer:

Date: Thursday, May 6, 2021 at 10:43 AM
To: "Lauer, Michael (NIH/OD) [E]" <michael.lauer@nih.gov>
To: Kristin West <KWest@cogr.edu>
Cc: Wendy Streitz <WStreitz@cogr.edu>; Robert Hardy <RHardy@COGR.edu>; Jackie Bendall <JBendall@COGR.edu>; Michael Lauer <michael.lauer@nih.gov>
Subject: Clarification on Yesterday's Blog Post Re. NIH NOT-OD-21-073 and NIH OD-21-110

Dear Mike,

Our members appreciated the publication of NOT-OD-21-110. It was our understanding that NOT-OD-21-110 clarified that NIH will not take enforcement action against institutions that do not use the new forms detailed in NIH NOT-OD-21-073 until Jan. 25, 2022.

We would like to confirm, based on our prior conversations with NIH, that this enforcement delay also applies to:

   a. the requirement to supply the supporting documentation specified in NOT-OD-21-073, whether that documentation is requested at JIT (or earlier if stated in the funding opportunity announcement); and
   b. the requirement to provide an electronic certification from the PI or other key/senior personnel.

We thought this was the case, but were confused by the Blog post yesterday which states as follows:

Applicants and recipients remain responsible for disclosing all research endeavors regardless of the version of the forms used, including:

   - Supporting documentation, which includes copies of contracts, grants or any other agreement specific to senior/key personnel foreign appointments and/or employment with a foreign institution for all foreign activities and resources that are reported in Other Support.
If the contracts, grants or other agreements are not in English, recipients must provide translated copies.

Can you advise whether:

(a) NIH is requiring recipients to disclose supporting documentation to NIH as of May 25, 2021; or

(b) NIH will not require that supporting documentation be disclosed to NIH until January 25, 2022, but institutions may be asked by NIH to provide them prior to this date, if necessary.

Finally, do you mind if we share your response with our members? We have received multiple emails last night and today seeking clarification on this point.

Many thanks for your consideration of this issue, and we look forward to hearing from you.

Best regards,

Kris

Kris West
Director Research Ethics & Compliance
COGR