

Changes to NIH Other Support Document Requirements

Plus Biosketch and Forms G

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Agenda

- Other Support Disclosure Requirements
- Other Support Document Signature Requirements
- Adobe Sign Instructions
- Flattening PDFs
- Post-Award Notification Requirement
- Biographical Sketch
- Forms G
- Questions



Other Support Disclosure Requirements



New Requirements!

March 2021
NIH Policy Notice NOT-OD-21-073

April 2021
NIH Policy Notice NOT-OD-21-110

- Implements several significant changes to the Other Support Document and the Biographical Sketch.
- Introduces new Biosketch and Other Support Document formats.
- · Expands scope of required documentation.

May 25, 2021
Partial Implementation

January 25, 2022 Full Implementation

What does the NIH use the Other Support Document to assess?

- All resources made available to an investigator, including any foreign activities, are considered prior to making an award
- Possible scientific and/or budgetary overlap
- Sufficient levels of effort are committed to the project
- Researcher time commitment and the potential for overlap or over-commitment (i.e. effort greater than 100%)
- Funds necessary to the approved project are included in the grant award

What must be included in the Other Support Document?

Financial Support

- Sponsored awards that support an investigator's research efforts, held at Cornell, at another institution/entity, or as an individual
- Consulting agreements when the PD/PI/KP will be conducting research as part of the consulting activities.
- Start-up packages from entities other than Cornell
- Institutional awards at Cornell or other institutions that are separately budgeted and accounted for (e.g. internal grants, but not gifts).

In-kind Resources

- In-kind contributions, e.g. office/laboratory space, equipment, supplies, support for laboratory personnel, and provision of high-value materials that are not freely available (e.g., biologics, chemical, model systems, technology, etc.), employees or students <u>supported by an outside</u> source.
- If the time commitment or dollar value of the in-kind contribution is not readily ascertainable, the recipient must provide reasonable estimates.

What **does not** need be included?

- Cornell start-up packages, gifts, or endowed chairs
- NIH training grants
- Non-financial resources that are available to the Cornell community at large, such as core facilities or shared equipment or other non-financial resources at Cornell not supported by an outside source
- Post-docs or graduate students funded through an external organization where the relationship with solely a mentor/mentee arrangement, with no research activities

New requirements effective January 25, 2022...

- Use of the new Other Support Document template is required.
- Financial and in-kind support is now in two separate sections
- Copies of foreign employment/appointment agreements and/or any agreements
 for foreign research support not administered by Cornell <u>must</u> attached to the
 Other Support Document submitted to NIH. If agreements are not in English, they
 must be translated to English prior to submission. *Please review with OSP
 prior to submitting to NIH*
- Other Support documents must be signed by the PI/PD/KP to certify that the information provided is complete and accurate



Other Support Signature Requirements

Signed Certification on Other Support Documents

- Signature block added for PD/PI/KP to certify the accuracy and completeness of the information provided
- Each PD/PI/KP must electronically sign their respective Other Support format as a PDF prior to submission
- Recipients and applicants may use the electronic signature software of their choice, and in alignment with their institutional practices
- A typed name, or a copy and paste signature, is not acceptable
- Signatures may not be delegated
- Applicants and recipients must maintain supporting documentation to reasonably authenticate that the appropriate individual signed the form and must make the documentation available upon request in accordance with 45 CFR Part 75.364
- Supporting documentation must be maintained by the unit
- OSP recommends the use of Adobe Sign (https://it.cornell.edu/e-sign)



Adobe Sign Instructions

Getting Access to Adobe Sign

Three groups of people involved in the e-signature process

Admins

- Designated person in each unit who assigns licenses, maintains groups within their unit, and provides primary technical support for their unit
- Units must enroll in the Electronic Signature service and designate an Electronic Signature Admin before anyone in that unit can use the service as a Sender

Senders

- Send forms in order to collect signatures
- Require a license (assigned by their unit's "admin")

Signers

- Only need to follow directions on how to sign an electronic form
- · No license required
- Can be Cornell or external

Getting Access to Adobe Sign

- Cornell has an enterprise-wide license (no license to Adobe Pro required)
- https://it.cornell.edu/e-sign
- Check with your unit administrator/IT office you may already have a designated administrator
- See https://it.cornell.edu/e-sign/sign-e-signature-service?utm_source=sidebar if your unit does not have a designated administrator
- Documents requiring signature can be sent from an EGA instead of a personal email (recommended) – this will make storing of signed documents easier



Getting Access to Adobe Sign

Do not wait until the last minute to look into access. It can take one to two days to get access.



OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

For New and Renewal Applications – DO NOT SUBMIT UNLESS REQUESTED PHS 398 OTHER SUPPORT

There is no "form page" for reporting Other Support. Information on Other Support should be provided in the format shown below.

*Name of Individual: Commons ID:

Other Support - Project/Proposal

*Title:

Major Goals:

*Status of Support:

Project Number:

Name of PD/PI:

*Source of Support:

*Primary Place of Performance:

Project/Proposal Start and End Date: (MM/YYYY) (if available):

* Total Award Amount (including Indirect Costs):

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (##_##)
1[enter year 1]	
2[enter year 2]	
3[enter year 3]	
4[enter year 4]	
5[enter year 5]	

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual: Commons ID:

IN-KIND

*Summary of In-Kind Contribution:

*Status of Support:

*Primary Place of Performance:

Project/Proposal Start and End Date (MM/YYYY) (if available):

*Person Months (Calendar/Academic/Summer) per budget period

Year (YYYY)	Person Months (##_##)
1[enter year 1]	
2[enter year 2]	
3[enter year 3]	
4[enter year 4]	
5 [enter year 5]	

*Estimated Dollar Value of In-Kind Information:

*Overlap (summarized for each individual):

I, PD/PI or other senior/key personnel, certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

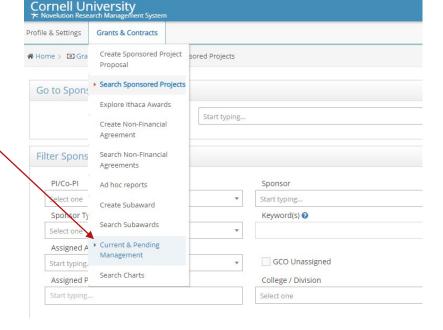
*Signat	ture:			
Date: _				

1. Use RASS to generate Other Support

2. Choose Other Support format

Selected Researcher	PI, Demo
Show Sponsor Format	Select one
	Cornell Standard
	DoD
	DoE
	NIH (format required after 1/25/2022)
	NIH (format before 1/25/2022)
	NSF

3. Scroll to bottom to "Print C&P Report"





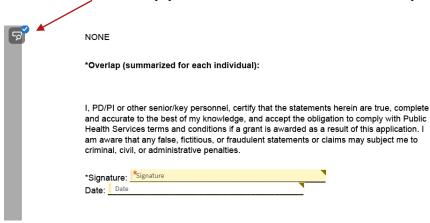


4. Review and edit Word version and save as PDF. **Note: PI should be involved in review and understand required disclosures.**

5: Login to Adobe Sign: https://esign.cornell.edu/ and click "request



- 7. Scroll to the page with signature and date block
- 8. Click box in upper left-hand corner to place signatures field:



9. Click "send".

10. Sender will receive a pop-up message in PDF

11. Sender will receive an email confirmation and the Signer will receive an email request to sign

12. Sender can change the alert settings to track the signature process

"NIH (format required after 1_25_2022)_Current_Pending (4)" has been successfully sent for signature

A notification has also been sent to you at mk636@cornell.edu for your records. "NIH (format required after 1_25_2022)_Current_Pending (4)" was sent for signature to mmklempa@gmail.com.

As soon as the agreement is complete, all eligible parties will be e-mailed PDF copies.

Reminders

There are no reminders set for this document

You will be alerted:

Change alert settings

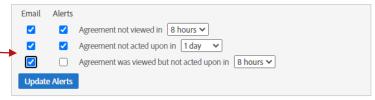
- . If the document you sent has not been viewed by today at 11:40 PM.
- . If the document you sent has not been signed by Dec 4 at 3:40 PM

All agreements that are not completed within 365 days will be automatically expired.

You will be alerted:

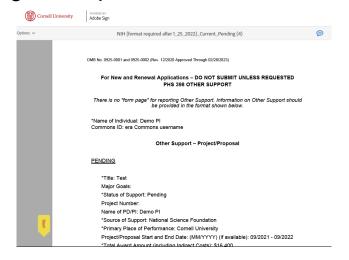
- If the document you sent has not been viewed by today at 11:40 PM.
- If the document you sent has not been signed by Dec 4 at 3:40 PM.

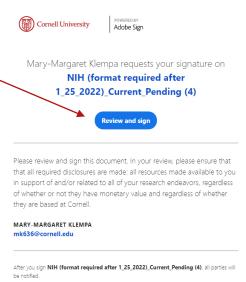
Hide alert settings



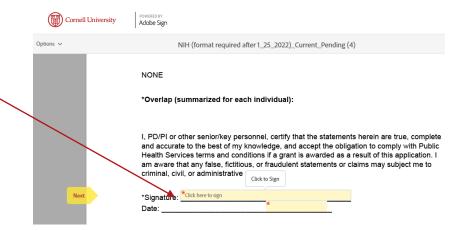


- 13. Signer will receive email with request to "Review and sign"
- 14. Adobe Sign will guide the Signer through the signature process





- 15. Signer will sign and submit
- 16. Sender and Signer receive emails confirming the document has been signed.
- 17. Signed document is maintained in the Adobe Sign account.



- 18. Other Support document can be downloaded and saved as a PDF from email confirmation.
- 19. Prior to uploading to eRA Commons, Other Support must be *flattened* and, in the case of multi-PD/PI/KP projects, uploaded as a single PDF after all signatures have been obtained.



Flattening Adobe Sign documents to PDF

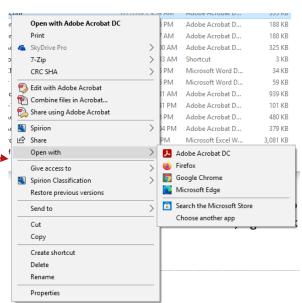
Option 1.

- Select "Download PDF" and save the document to a file
- In the printer drop-down menu of the saved PDF, select the "Microsoft Print to PDF" option to properly "flatten" the signed Other Support page.
- After doing so, the Signer/Sender should retain a copy of the original Adobe Sign document and a copy of the "flattened" version of the signed Other Support document.

Flattening Adobe Sign documents to PDF

Option 2

- Select Download PDF and save to your files
- From file location, right click to display menu and click "Open with..."
- Open PDF into the browser of your choice
- From browser, open menu in top right hand corner and select "Print" and then "Save as Adobe PDF"



- A flattened PDF removes the "Certified by Adobe Sign..." blue band and any hyperlinks
- If the PDF is not flattened, it may cause errors in the eRA Commons
- Contact your unit IT group if you have trouble with the flattening process

Summary of Key Points

- PDs/Pls/KP must sign Other Support documents submitted through the JIT and RPPR process certifying that the information provided is complete and accurate
- Units must maintain documentation on file to reasonably authenticate that the appropriate individual signed the form.
- Units must have a "Unit Admin" who can assign licenses to Senders
- Check with your unit IT to determine whether you have a Unit Admin
- If you do not have a "Unit Admin", contact the Adobe Sign team: https://it.cornell.edu/e-sign/sign-e-signature-service?utm_source=sidebar
- Do not wait until the last minute to lookinto access
- Other Support documents must be "flattened" prior to upload to eRA Commons



Other Support Post-Award Notification Requirement

Post-Award Notification Requirement

- When a recipient organization discovers that a PI or other Senior/Key
 personnel on an active NIH grant failed to disclose Other Support information
 outside of Just-in-Time or the RPPR, as applicable, the recipient must submit
 updated Other Support to the Grants Management Specialist named in the
 Notice of Award as soon as it becomes known.
- Pls and campus research administrators are expected to reach out to their assigned Grant & Contract Officer should any undisclosed Other Support information be discovered.



Biographical Sketch

What must be included in the Biosketch?

- All currents position or scientific appointments held by investigators
- Includes domestic or foreign, paid or unpaid, or full/part-time/voluntary.
- Titled academic, professional, or institutional appointments, including adjunct, visiting, or honorary must be disclosed.
- Outside activities that are not research related (e.g. serving on a science advisory board for a start-up company where the investigator will not perform research) do not need to be included in the disclosure, but may still require disclosure to Cornell in the annual financial conflict of interest (fCOI) disclosure.

Effective January 25, 2022

- Section A, Personal Statement
 - All applicants may now include details on ongoing and completed research projects from the past three years that they want to draw attention to (previously known as Research Support).
- Section B, Positions, Scientific Appointments, Honors
 - This section has been expanded to require disclosure of all current positions and scientific appointments both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).
- Section D, Research Support and/or Scholastic Performance
 - This section has been removed for non-fellowship applications and RPPRs.
 - Section D is solely present on the fellowship version of the Biosketch, and no longer includes research support, only Scholastic Performance.

Current	Requi	irements	

- All senior and key personnel **must** report all support related to their
 - research activities whether funded or in-kind, domestic or foreign, held at Cornell or another institution or privately in the Other Support Document provided with a JIT or RPPR submission.
- All positions and scientific appointments whether paid or unpaid, domestic and foreign – including affiliations with foreign entities or governments <u>must</u> be disclosed in the Biosketch.
- Use of the new Other Support Document and Biosketch templates is encouraged but not required.
- Translated copies of foreign employment/appointment agreements and any agreements for foreign support listed on the Other Support Document <u>must</u> be available if requested by Cornell or NIH.
- Consulting agreements, when the PD/PI or other senior/key personnel will be conducting research as part of the consulting activities must be included in Other Support.
- All researchers and administrators <u>must</u> notify the assigned Grant & Contract Officer immediately upon discovering previously undisclosed Other Support.

All previous requirements, **plus**:

 New Other Support Document and Biosketch templates <u>must</u> be used.

Effective January 25, 2022

- Translated copies of foreign employment/appointment agreements and any agreements for foreign support listed on the Other Support Document <u>must</u> be provided to Cornell and attached to the Other Support Document submitted to NIH.
- All Other Support Documents **<u>must</u>** be signed by PI/PD/KP.



Forms G

Significant Changes to Forms G

- Updated the expiration date on each form
- DUNS replaced with UEI on various forms Cornell's UEI can be found at https://researchservices.cornell.edu/resources/institutional-profile-and-duns-number (G56PUALJ3KT5)
- Updated Country and State lists on various forms
- Budget Forms: Within section F, Other Direct Costs, increased the number of available "Other" direct cost lines from 3 to 10
- PHS Fellowship Supplement: Added new "Childcare Costs" section in Budget
- PHS Human subjects and Clinical Trials Information Study record changes:
 - Under 3.2, changed the "If yes, describe single IRB plan" attachment field label to "Single IRB plan attachment"

NIH Resources

- Other Support Format Pages, Instructions and Samples
- Biosketch Format Pages, Instructions and Samples
- FAQs
- NOT-OD-19-114, Reminders of NIH Policies on Other Support and on Policies related to Financial Conflicts of Interest and Foreign Components (July 2019)
- NOT-OD-21-073, Upcoming Changes to the Biographical Sketch and Other Support Format Page for Due Dates on or after May 25, 2021 (March 2021)
- NOT-OD-21-110, Implementation of Changes to the Biographical Sketch and Other Support Format Page (April 2021)

Cornell Resources

- Disclose Foreign Collaborations and Support
- Disclosing International Partnerships to Cornell and External Sponsors
- NIH: Disclosing Other Support and Foreign Components
- NSF: Disclosing Current & Pending Support, Biographical Sketches, and International Partnerships
- NASA: Affiliations with China and Disclosing Current & Pending Support



Questions