NEW NIH REQUIREMENTS FOR BIOSKETCH AND OTHER SUPPORT

RESEARCH MANAGEMENT MEETING – MAY 20, 2021

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INTRODUCTIONS

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OVERVIEW

NIH has made some changes & clarifications to their Other Support and Biosketch templates and requirements to address challenges relating to disclosure of information and foreign involvement.

The timing of the required implementation is split:
• Items considered clarifications are required immediately
• New requirements are delayed until January 25, 2022
OVERVIEW

Changes to Biosketch

Changes to Other Support

• Signature required by PI/Program Director or Other Senior/Key Personnel on Other Support to certify the accuracy of the information submitted

• Copies of foreign agreements which include a research component must be submitted and translated to English
WHAT CHANGES IMMEDIATELY

What must be disclosed?

- ALL research-related endeavors
- Includes Outside Activities (20% time) & summer months
- May include consulting
- Internal awards
- Gifts with terms and conditions
WHAT CHANGES IMMEDIATELY

Who must disclose?

- PIs and Co-PI
- Senior and Key Personnel
- May include Collaborator or Consultants
WHAT CHANGES IMMEDIATELY

When do we disclose?

• Immediate notification of previously undisclosed Other Support
  • What is an undisclosed item?
    • A failure to report an activity related to research on a previous Other Support or RPPR
  • New activities go on future reports
BIOSKETCH

• Strong recommendation to switch to SciENcv for the Biosketch
• Major change is what needs to be included - regardless of form or format used
• Using the new format version of SciENcv includes all the items that must now be disclosed
BIOSKETCH

Forms and Formats

Create a New Document

Document name
Enter a name to help you to identify this document

Format
- NIH Biosketch (March 2021)
- NIH Biosketch
- NIH Fellowship Biosketch (March 2021)
- NSF Biosketch
- NSF Current and Pending Support
- IES Biosketch

Select a format for this document

Biosketch available for optional use as of March 2021. Use of this version is required for applications with the due dates on or after May 25, 2021.
EXPANDED INFORMATION REQUIRED – BIOSKETCH
SECTION B

Section B will be renamed to “Positions, Scientific Appointments, and Honors.”

The NIH specifies that the items should be listed in reverse chronological order & include:

• All positions, both domestic and foreign
• All scientific appointments, both domestic and foreign
• All affiliations with foreign entities or governments
• All 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)
• Any relevant academic and professional achievements and honors.
Section A “Personal Statement”

• May include *ongoing and completed research projects from the past three years* that the PI wants to draw attention to
  • Previously known as Research Support
  • If using the current format, add this to the end of their Personal Statement
OTHER SUPPORT

- Utilize CURRENT forms and format for Other Support
- New form/format will not be used until we develop an approach for completion & review

<table>
<thead>
<tr>
<th>FORMAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME OF INDIVIDUAL</td>
</tr>
<tr>
<td>Project Number (Contact Principal Investigator) Source Title of Project (or Subproject)</td>
</tr>
</tbody>
</table>

OVERLAP (summarized for each individual)
WHAT CHANGES IN JANUARY 2022

• New forms for Other Support & Biosketch
• Copies of all foreign agreements that involve research, translated into English
• Signatures of PI and key personnel on Other Support forms
FOR WHOM IS OTHER SUPPORT REQUIRED?

Other Support information is required for:

• All individuals designated in an application as **Senior/Key Personnel**, except
  • Program directors, training faculty, and other individuals involved in the oversight of **training grants**
  • Individuals categorized as **Other Significant Contributors**

RPPRs updates:

• All senior/key personnel working on the project must disclose when there has been a change to their previously disclosed Other Support
Updated Requirements for Recipients (NOT-OD-21-073):

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

- **Immediate notification of undisclosed Other Support**. When a recipient organization discovers that a PI or other Senior/Key personnel on an active NIH grant failed to disclose Other Support information in 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.
Updated Requirements for Recipients (NOT-OD-21-073):

- **In-Kind Contributions.** The format page has been re-organized to separate funded projects from in-kind contributions.

- **Signature Block added.** A signature block has been added for Program Director/Principal Investigator or Other Senior/Key Personnel to certify the accuracy of the information submitted. Each PD/PI or senior/key personnel must electronically sign their respective Other Support form as a PDF prior to submission.
  - Must be the PI/key personnel signature – NO proxy signatures allowed.
WHAT DO THE NEW REQUIREMENTS MEAN?

• **New Items**
  - Same format for JIT and RPPR
  - Investigators to list active, pending, AND completed (within the last 3 years) support
  - In-kind support to be listed in a separate section
  - PI/PD certification and signature required
  - Supporting documentation (and translations)
  - Report research-related consulting

• **Clarified Items**
  - Notification requirement for unreported items
  - Gifts
  - Project specific overlap statement required
OTHER SUPPORT: SUPPORTING DOCUMENTS

• What supporting documentation is required?
  • Any signed foreign agreement or appointment that includes research
    • Copy of agreement, in English
    • Includes consulting when the individual will be conducting research as part of the consulting activities

• Machine translations such as Google Translate are acceptable
ROLE OF STAFF

• Staff is NOT responsible for completing the forms
• Staff CAN assist the PI in obtaining data and drafting forms
• PI is RESPONSIBLE for completion and accuracy
• PI MUST keep disclosure information in OAIR up to date
• PI MUST inform OSP/ORA if adding previously undisclosed information (this must be reported immediately to NIH)
• PI MUST gather and report information that is outside of Harvard systems
• School Compliance Offices will be available as a resource for discussion of complex scenarios
SOURCES OF INFORMATION FOR OTHER SUPPORT

Harvard GMAS

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.
INFORMATION REQUIRED FOR OTHER SUPPORT - NOT IN HARVARD SYSTEMS

Examples of information required for Other Support that may not be in Harvard Systems include, but are not limited to:

• A list of all participants and collaborators in his/her lab
  • Identify externally funded students, post-docs and visitors (in-kind)
  • Document calendar months

• An inventory of all in-kind contributions (i.e. samples, computing, sequencing, space, equipment)

• Any research activities outside of Harvard

*Note that broadly available resources (startup funds, core facilities) don’t need to be reported on Other Support pages
COMMUNICATION

• Between now and January 25, 2022 (and beyond):
  • School info sessions
  • Faculty & staff training
  • Identify school resources
  • Develop & make available resources
  • Post information on OVPR website
RESOURCES

• FAQ’s
• Step-by-Step Guide for Faculty and Staff
• Conversation Guide for Other Support
• NIH Agency Chart providing guidance on where to report
• Biosketch Template showing what changes
• Other Support Template showing what changes
• Agency Website Resources
• School identified key resource for questions
OPEN ITEMS

- Definition of Research
- Managing subaward disclosure
- PI signature process on Other Support
- Process for review of Other Support
- External foreign contracts involving research (storage, review, redaction)
- 5-day rule & timing of reviews of JIT and RPPR’s
- Clarification on R&Rs