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Sent: Tuesday, May 25, 2021 2:33 PM
To: Kuszmar, Eleanor <Eleanor_Kuszmar@hms.harvard.edu>
Subject: New NIH Requirements and Upcoming Info Sessions



Dear HMS Faculty and Research Staff:

We are writing to make you aware of a significant notice from the NIH, [NOT-OD-21-073](#), that announced updated Biosketch and Other Support format pages and instructions for use in applications, Just-in-Time (JIT) Reports, and Research Performance Progress Reports (RPPRs). Details are found in the summary at the bottom of this email. We want to brief you on the steps underway at HMS to ensure compliance in advance of the notice's required implementation date of **January 25, 2022**, and to inform you of upcoming opportunities for you to learn more and ask questions. It is important to note that while the implementation date may seem a long way off, NIH has signaled its expectation that researchers are complying with the heightened disclosure mandates reflected in updated templates immediately even if their institution has not yet adopted the new forms. *Accordingly, it remains crucial that researchers **fully understand their Other Support disclosure obligations as communicated by Research Administration throughout this past year, particularly as those apply to relationships with and/or resources (including personnel) available from foreign institutions.***

NOT-OD-21-073 also adds new administrative requirements, including (i) signatures from PIs and senior/key personnel on Other Support submissions to certify the accuracy of each individual's submission, (ii) reporting consulting activities when the consultant will be conducting research as part of the outside activity; and (iii) appended copies of personal consulting agreements, contracts, grants, or any other agreements specific to senior/key personnel foreign appointments, affiliations, and/or employment with a foreign institution, including consulting for research with a foreign institution. If any agreement is in a

foreign language, the NIH is requiring that it be translated. In addition, **the NIH now expects immediate notification** when a recipient organization discovers that a PI or other senior/key personnel on an active NIH grant failed to disclose Other Support information.

We are working closely with the University to provide additional guidance on the process that will be rolled out for review and, as needed, redaction of agreements that will require appending as of January 25, 2022. We encourage faculty to seek guidance immediately from one of the contacts below if there are questions and concerns with existing arrangements to which the new submission requirements may apply.

The Office for Research Administration and the Office for Research Compliance will conduct optional brown bag zoom sessions in the coming weeks to provide additional guidance on this topic. These sessions will be open to all research faculty and administrative support staff and will occur at the following dates and times:

June 10, 11 a.m. – noon (focus on **administrative** audience, but all are welcome)

June 11, 10 – 11 a.m. (focus on **researcher** audience, but all are welcome)

July 8, 11 a.m. – noon (focus on **researcher** audience, but all are welcome)

July 9, 10 – 11 a.m. (focus on **administrative** audience, but all are welcome)

We are also in the process of updating the [HMS Research Influence](#) website to reflect the recent notices and will provide additional FAQs and guidance as we learn more. We continue to work closely with the University, our affiliate partners, and the wider academic community to ensure that we are following best practices. We ask for your patience and collaboration as we work together to ensure that we provide the most up-to-date and accurate information on this evolving topic.

We look forward to seeing many of you with questions at the upcoming brown bag sessions.

Sincerely,

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Summary of New Requirements & Related Resources

The clarifications in [NIH-OD-21-073](#) include:

Biographical Sketch Format Page (due with all new proposal submissions)

- New Biosketch templates or use SciENCv
- Section A. Personal Statement may include details on ongoing and completed research projects from the past three years that they want to draw attention to
- Section B. Positions and Honors has been renamed Positions, Scientific Appointments, and Honors.
- Section D. This has been removed for non-Fellowship Biosketches. For Fellowship Biosketches, Section D has been updated to remove Research Support.

Other Support Format Page (due with all Just-In-Time and RPPR submissions for due dates on/after January 25, 2022.) **Requires immediate implementation steps**

- New Other Support template
- Signature required for PI or senior/key personnel to certify accuracy of submission
- **Include all resources made available to a researcher in support of and/or related to ALL of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant. This includes:
 - Resource or financial support from all foreign and domestic entities that are available to the researcher. This includes, but is not limited to, financial support for laboratory personnel and provision of high-value materials that are not freely available (e.g., biologics, chemicals, model systems, technology). Institutional resources, such as core facilities or shared equipment that are more broadly available should not be included in Other Support, but rather listed under Facilities and Other Resources.
 - Consulting Agreements when the PI or senior/key personnel is *conducting research (see below for working definition)* as part of the consulting activities
 - In-kind contributions e.g., office/laboratory space, equipment, supplies or employees or students supported by an outside source
- For any foreign appointments, employment or outside activities that involve conducting research as part of consulting, senior/key personnel must attach a copy of their agreement with the foreign entity.
 - Agreements in a foreign language must be translated into English (Google Translate OK).
 - **Have been reviewed by HMS for compliance with HMS policies prior to submission of the Other Support.

Conducting research as part of consulting is defined as any consulting activity that results in earning authorship on a publication describing or

supporting a research activity^[i] or any consulting activity that meets the NIH definition of [Research and Development](#) as defined in the [NIH GPS^{\[ii\]}](#) or research as defined by the Federal Policy for the Protection of Human Subjects, or the “Common Rule.”

OTHER IMPORTANT REQUIREMENTS AND AVAILABLE RESOURCES

Biosketch Resources

Resources in support of NIH Biosketches

- [NIH Biosketch Resources](#)
- [Non-Fellowship Biosketch Instructions](#)
- [Non-Fellowship Templates](#)
- [Sample Non-Fellowship Biosketch](#)
- [SciENCv](#)
- [Fellowship Biosketch Instructions](#)
- [Fellowship Template](#)
- [Sample Fellowship Biosketch](#)

Other Support Resources

- [NIH Other Support Resources](#)
- [NIH Other Support Instructions](#)
- [NIH Other Support format page](#)
- [NIH Other Support Sample](#)
- [NIH Other Support FAQs](#)

General Support & Resources at HMS

- For questions regarding when to seek prior approval for a foreign component or what to disclose in your Biosketches, grant applications or Other Support pages, please contact your awards officer in the Office of Research Administration. You may contact ORA directly at international_collaborations@hms.harvard.edu.
- For questions regarding your Outside Activities Reporting obligations, please contact the Outside Activities Program in the

Office for Academic and Research Integrity at 617-432-1343 or outside_activities@hms.harvard.edu.

- Please direct all other questions to the Research Compliance team within the Office for Academic and Research Integrity at 617-432-1343 or ari@hms.harvard.edu.

[i] Authorship should be earned and assigned in accordance with the [HMS Authorship Guidelines](#), which state that everyone who is listed as an author should have made a substantial, direct, intellectual contribution to the work. For example (in the case of a research report) they should have contributed to the conception, design, analysis and/or interpretation of data. Honorary or guest authorship is not acceptable. Acquisition of funding and provision of technical services, patients, or materials, while they may be essential to the work, are not in themselves sufficient contributions to justify authorship.

[ii] The NIH GPS (<https://grants.nih.gov/policy/nihgps/index.htm>) defines Research and Development as: All research activities, both basic and applied, and all development activities that are performed by HHS award recipients. The term research also includes activities involving the training of individuals in research techniques where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function. "Research" is defined as a systematic study directed toward fuller scientific knowledge or understanding of the subject studied. "Development" is the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes.

The Common Rule defines research as a systematic investigation – including research development, testing and evaluation – designed to develop or contribute to generalizable knowledge.

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