Harvard University Guide to NIH Biosketch and Other Support Disclosures

Introduction

This document is intended to help reporting individuals (i.e. researchers and/or Key Personnel) identify and catalogue resources and activities that must be reported in NIH grant documents. This guide may also help administrators support faculty in preparing accurate and complete submissions of Biosketches at proposal stage and Other Support for Just in Time and RPPR requests.

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1. Overview

Background Information

Over the course of 2021, NIH posted several notices updating its submission requirements and Grants Policy Statement. The requirements for submissions on or after January 25, 2022 are outlined on the OVPR Website. Relevant changes include:

- 1. Revisions to Biosketch Sections A, B, and D
- 2. Changes to Other Support
 - **a.** Separation of funded projects and in-kind contributions into different sections.
 - b. Signature block added for Key Personnel to certify the accuracy of the information submitted. Each PD/PI and other senior/key personnel must electronically sign their Other Support form as a PDF prior to submission. See "<u>Electronically Sign and Certify a PDF</u> <u>Document</u>" for details.
 - **c.** For Other Support submissions that include foreign activities and resources, copies of contracts, grants, and any other agreement specific to foreign appointments, employment or other affiliations of the key personnel completing the document must be attached. An English translation must be provided if the original document is in a foreign language.
 - **d.** If an organization discovers that a PI/Key person failed to disclose Other Support information outside of JIT or the RPPR, the institution must submit updated Other Support to the Grants Management Specialist named in the Notice of Award as soon as it becomes known.

For purposes of this document, investigators are encouraged to review the applicable NIH guidance (Notices, FAQs, Grants Policy Statement) pertaining to the format and content of the Biosketch and Other Support sections. Note that guidance included in notices supersedes guidance in the FOA and application guide.

- i. <u>NOT-OD-21-073</u>
- ii. Biosketch format, samples, and instructions
- iii. Other Support
- iv. NIH FAQs (Biosketch, Other Support and Foreign Components)
- v. Grants Policy Statement (revised December 2021)

Additional resources for proposal preparation and disclosure requirements are available through your sponsored research office and OVPR; please refer to section 9 for specific School Contact information.

2. Biosketch

- A. Engage your sponsored research office early in the application process. Developing and submitting a grant application is a team effort. Your sponsored research office can:
 - Help ensure you are registered in the <u>eRA Commons</u>;

- ii. Guide you through the application process and inform you of any institutional deadlines you must meet (OSP, HMS ORA, Harvard Chan SPA, RAS FAS);
- iii. Provide guidance on NIH policies and processes;
- iv. Offer specific advice on developing a new proposal (OSP, HMS ORA, Harvard Chan SPA, RAS FAS); and
- v. Plan your timeline to ensure your application meets all applicable deadlines, especially when a proposal involves collaborating institutions.
- B. Download and carefully read the applicable <u>NIH funding opportunity announcement (FOA)</u>. Use the instructions in the announcements in conjunction with the <u>application guide</u> to prepare your application. If instructions conflict, follow the FOA.
- C. *Update your Biosketch* per NIH Notice <u>NOT-OD-21-073</u> with the following:
 - Section A: Applicants may now include details on ongoing and completed research projects from the past three years that they want to draw attention to within the Personal Statement.
 - II. **Section B**: Renamed "Positions, Scientific Appointments, and Honors." The NIH specifies that the list <u>must</u> include the following current appointments and affiliations, whether remuneration is received and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary), including:
 - 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
 - Any relevant academic and professional achievements and honors
 - III. **Section D:** Removed from the non-Fellowship Biosketch. For the Fellowship Biosketch, Section D has been updated to remove "Research Support."

Submissions requiring Other Support:

• Just-in-Time Submissions

NIH uses Just-in-Time (JIT) procedures for certain programs and award mechanisms (each FOA will include specific guidance on applicable requirements). These procedures allow certain elements of an application, including Other Support documentation, to be submitted later in the application process once the application is under consideration for funding. Applicants are responsible for promptly notifying NIH of any substantive changes to previously submitted Just-in-Time information up to the time of award.

Just-In-Time submissions now require a JIT request be created in GMAS. The request will allow us to efficiently track JIT requests and review the Other Support, including any foreign agreements that will need to be included with Other Support as supporting documentation. Note that submitting offices will need time to review and submit responses to Just-In-Time requests.

Documents will not be submitted without a complete and thorough review by the submitting office.

For your reference, a GMAS Just-In-Time Job Aid is available.

Research Performance Progress Report (RPPR)

The RPPR (Annual, Final, and Interim) is used by grantees to submit progress reports to NIH documenting accomplishments and compliance with the terms of the award during the lifecycle of the grant. Additional information regarding the content, submission process and due dates for each type of RPPR may be found in the <u>NIH RPPR Instruction Guide</u> and <u>NIH RPPR page</u>. For the <u>annual RPPR</u>, a revised Other Support form is required if there have been any changes since the previous submission.

Submitting offices will need time to review and submit progress reports. Documents will not be submitted without a complete and thorough review by the submitting office.

3. Prepare an Inventory of In-Kind Support and Other Resources

All Harvard individuals who are designated as Key Personnel on an NIH award/subaward are required to report all their research support to NIH via the Other Support form, which is required at JIT and with each RPPR if their support has changed since the last submission. To provide a complete list of resources and support, all Key Personnel must take inventory of all resources provided or otherwise supported externally and available in support of their research. This may include:

- Supplies and Equipment, including high value material that is not broadly available.
- Facilities, including any office/lab space or other facilities that are not Harvard owned or leased, and not otherwise made broadly available. *Note that institutional resources, including core facilities or shared equipment, should not be included as Other Support, but instead listed under Facilities and Other Resources within the proposal application.
- **Personnel**, including postdoctoral researchers, students, and other lab personnel, paid from an external source or self-funded and working on the research of the reporting Key Person.
- Other In-Kind Resources, including Research Collaboration Agreements (RCAs) or other agreements or commitments that may involve the performance of research or exchange of resources in support of your research endeavors. This includes DUAs and MTAs if the exchange covers high value data/materials that are not broadly available.
- Outside Funding Support, including funding received directly or through another entity at which you have an affiliation (including the Harvard Affiliates). This includes external start-up packages.

There are two options for collecting Harvard system information pertaining to potential sources of in-kind and other resources. Please note, the two options are only available to individual Key Personnel; no one else has access to the OAIR report or the GMAS Other Support and Activities report:

- (1) Download the GMAS report (which includes data from OAIR and Agreements Modules) through a direct link to your Other Support and Activities.
- (2) Export your current activities separately from OAIR, GMAS, and Agreements systems

Any resources made available to you outside of a formal agreement, or through an agreement not captured in OAIR, GMAS or the Agreements module, should also be included in your inventory.

4. Downloading Your Other Support and Activities Report in GMAS

Each researcher can download their Other Support and Activities report (Excel file). This report includes their sponsored projects and billing agreements in GMAS, selected information from their OAIR reporting, and their data use agreements from the Harvard DUA-Agreements module.

Grant managers can access a report of their PI's Active and Pending sponsored projects and billing agreements from GMAS by searching for the individual's name using the "People" link in the top GMAS navigation bar, then clicking the "Active and Pending Projects (download)" link to download the Excel file. The individual's report will contain rows for every active and pending project in GMAS where they are members of a Research Team. The report will also contain rows for every project where the person is charged to the project in PeopleSoft. This information may be used to help facilitate completion of Other Support forms with respect to current and pending Harvard sponsored projects.

5. Export Your Current Outside Activities from OAIR

Although the GMAS Other Support and Activities report includes disclosure information from the individual's OAIR record that are likely to require reporting on Other Support and Biosketches, reporting individuals may want to review the full list of their OAIR disclosures. From the **My Disclosures** tab in OAIR, each researcher can export a list of their current active outside activities and interests. For specific instructions:

Exporting Current Outside Activities from OAIR

The downloaded file will include only the summary disclosure information displayed on the My Disclosures tab. This export option can be used to help facilitate completion of the <u>Biosketch and Other Support</u> forms for NIH submissions as they relate to outside appointments, affiliations, employment and other outside activities that may require disclosure.

As an initial step, you should identify those appointments and other activities based on the OAIR download which involve a research component. Those activities (including consulting) which involve research will need to be captured as either an In-Kind Resource or as an Other Resource on the Other Support.

Harvard University Definition of Research

Adheres to the <u>Federal Policy for the Protection of Human Subjects</u> (known as the "Common Rule" as defined in HHS regulation <u>45CFR46</u>). Teaching/training in research methods may also constitute Research for the purposes of NIH's definition.

The Common Rule defines research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (45CFR46.102(I))

Harvard University Definition of Conducting Research

To be a Project Director, Principal Investigator or to otherwise be responsible for the design, conduct or reporting of research regardless of title or position (e.g., an Investigator). This definition does not normally include service on scientific or clinical advisory boards or more general scientific consulting unless it is anticipated that the individual will make a direct and significant intellectual contribution to a specific research project for the entity.

If any of your consulting/outside appointments involving a research component are for a non-US entity or institution, you'll need to collect a copy of any contract or agreement between you and the entity/institution. If the contract is in a foreign language, both the unredacted original and an unredacted English translation must be made available. Machine translations (e.g., Google Translate) are acceptable. Original agreements and translations must be uploaded to GMAS. To do this, sign into GMAS using your HarvardKey and click on your name at the top right corner of the GMAS home page. Select "Profile" from the pull-down menu to navigate to your Person profile. Scroll down to the "Outside foreign contracts and agreements" section and click on the "Upload" button to select (or drag and drop) the contract/agreement files. View the Outside foreign contracts and agreements document repository job aid.

6. Export your active DUAs from the Agreements Module

Each researcher can also access a list of their active DUAs by way of the Agreements-DUA module:

Exporting Data Use Agreements from the DUA module

The downloaded file will include for each DUA and amendment: the data provider name, any highlighted terms, and a link to the Agreements record for further details. While most DUAs do not comprise Other Support, this information can assist with the identification of any data sources that are both high value and not broadly available and thus require disclosure.

7. Submitting your NIH Applications, JIT Info, and RPPRs

Complete proposal applications, Just-In-Time (JIT) information, and progress reports (RPPRs) are due to your School's submitting office for review and authorization according to their deadline policy. Use the links below for additional information on the specific deadline policies for each submitting office.

- For submissions to <u>OSP</u>
- For submissions to <u>HMS ORA</u>
- For submissions to Harvard Chan SPA

8. Roles & Responsibilities

Step	Role	Task/Activity		
 "Disclosing Other Support: Guidance for Faculty and Key Other Support as part of a JIT request or RPPR Keep disclosure information in OAIR up to date Provide research support information to your grants manager recorded in Harvard systems Review the NIH Agreement Disclosure Flowchart to help ideas submitted as supporting documentation to Other Support. The Flow Chart (MP4) walks through the flow chart process Upload foreign agreements to your Person profile in GMAS for as possible, well in advance of JIT or RPPR submissions. View the agreements document repository job aid Be responsible for completeness and accuracy of Biosketches Once reviewed and approved by Central Reviewer, certify electronic signature. See How to "Electronically Sign a PDF" Inform your central submitting office of any previously undiscentifications. 		 "Disclosing Other Support: Guidance for Faculty and Key Personnel" prior to submitting Other Support as part of a JIT request or RPPR Keep disclosure information in OAIR up to date Provide research support information to your grants manager, including information not recorded in Harvard systems Review the NIH Agreement Disclosure Flowchart to help identify which contracts need to be submitted as supporting documentation to Other Support. The video of the NIH Agreements Flow Chart (MP4) walks through the flow chart process Upload foreign agreements to your Person profile in GMAS for School Central review as soon as possible, well in advance of JIT or RPPR submissions. View the Outside foreign contracts and agreements document repository job aid Be responsible for completeness and accuracy of Biosketches and Other Support forms Once reviewed and approved by Central Reviewer, certify Other Support information via 		
2	Dept. Grant Manager	 Complete the informational module in the Harvard Training Portal (HTP) "Disclosing Other Support: Guidance for Faculty and Key Personnel" Set appropriate expectations with researchers regarding submission timelines Assist reporting individuals by directing them to NIH and Harvard resources on disclosures Compile disclosure information from PIs and format it using NIH and Harvard instructions, templates, and FAQs Ensure JIT and RPPR requests are entered in GMAS (including when Harvard is a subrecipient) and that Central Reviewer has signed off in GMAS prior to submitting any OS documents. Work with Central Reviewer to address any questions or concerns regarding content or process for Biosketches or Other Support documents. 		

9. School Contacts

Foreign Contract and Agreement Review Contact by School				
School	Main Contact	Email address		
FAS	Lauren Ferrell	Outsideactivities@fas.harvard.edu		
GSE	Tiffany Blackman	tiffany_blackman@harvard.edu		
HMS HSDM	Lindsay Monahan	international_collaborations@hms.harvard.edu		
SPH	Angela Brazeau	oscontracts@hsph.harvard.edu		
HKS	Carrie Kachoria	carrie_kachoria@hks.harvard.edu		
SEAS	Lauren Ferrell	Outsideactivities@fas.harvard.edu		
HLS	Katie McGrath	kmcgrath@law.harvard.edu		
Wyss	Katrin Duevel	katrin.duevel@wyss.harvard.edu		
Other Schools	Cont	act your OSP Rep with Questions		

General Questions about Biosketch, Other Support and Current & Pending				
School	Main Contact	Email address		
FAS	Lauren Ferrell	research@ras.harvard.edu		
GSE	Tiffany Blackman	tiffany_blackman@harvard.edu		
HMS HSDM	Kelly Evans	Kelly Evans@hms.harvard.edu		
SPH	Melissa Francis	mjfrancis@hsph.harvard.edu		
HKS	Carrie Kachoria	carrie_kachoria@hks.harvard.edu		
SEAS	Pam Baker-Webber	bakerwebber@fas.harvard.edu		
HLS	Katie McGrath	kmcgrath@law.harvard.edu		
Other Schools	Conta	act your OSP Rep with Questions		

9. Examples of Resources Available

Resources Available Now on the OVPR Website: Resources for Faculty and Administrator include, but not limited to:

- Training modules
- How to documents
- NIH Agreement flow charts
- NIH Foreign Component Decision documents
- FAQ's
- Other Support Guides and templates

Appendix A -Guide to Help Reporting individuals with Disclosing Resources and Activities for NIH Grant Submissions and Funded Awards

This guide is designed to help reporting individuals identify and catalogue resources and activities that must be reported in your Biosketch and Other Support. This guide may also help administrators support faculty in preparing accurate and complete submissions that report all necessary activities and resources.

Biosketch

Section B Positions, Appointments and Honors List in reverse chronological order all domestic and foreign positions and scientific appointments, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary). Use of SciENcvⁱ is recommended for the NIH Biosketch format.

Biosketch Section B

- Review active positions, titles, and appointments on your CV
- Run <u>Other Support and Activities</u> Report from GMAS to assist with review of positions, titles, and appointments
- Review all appointment or employment letters
- Google yourself to see how other organizations list you

Foreign Appointments, Employment, Affiliations, Resources and Research Activities

NIH requires reporting individuals to provide copies of foreign contracts, grants, or any other agreements specific to senior/key-personnel foreign appointments, affiliations, and/or employment with a foreign institution for all foreign activities and resources that are reported in Other Support. NIH also requires that reporting individuals provide copies of foreign agreements when the outside activity involves Conducting Research as Part of Consulting. Copies must be provided as part of the PDF following the Other Support format page, and when necessary, must be translated into English (note that a freeware translation service (e.g., Google Translate) is acceptable).

Foreign appointments, employments and affiliations should be listed on your **Biosketch**. **Resources** associated with those appointments must be included on your **Other Support**. **Agreements** for such resources, or for conducting research, must be **attached to your Other Support**.

Foreign Appointments, Employments, and Affiliations

- Compile a list of all foreign outside activities, appointments, and employments. Run report in OAIR to assist with review.
- Review all outside activity arrangements, letters, or agreements, to assess for any foreign outside activity that provides employment, affiliation, or appointment through that foreign entity/institution.
- List all foreign employments, affiliations, or appointments on your biosketch.

• If you have a grant, contract, or other type of agreement with a foreign entity, and if the agreement involves either (i) the conduct of research or (ii) the provision of resources to support your research, the foreign agreement and an English translation of the agreement must be appended to the end of your Other Support document. If the agreement provides a resource that supports your research endeavors, also list the resource on your Other Support document.

Attaching foreign contracts/agreements/grants when related to a foreign employment, affiliation, or appointment:

- All foreign agreements (including English Translation, if needed) specific to foreign
 appointments, affiliations, and/or employment with a foreign institution should be
 uploaded to your GMAS person profile (GMAS Job Aid for Outside Foreign Contracts
 and Agreements). An email will be sent to your school's reviewing office indicating
 there is a foreign agreement pending review for potential disclosure on and
 attachment to your Other Support Page
- Please see <u>Contract and Agreement Review and Reporting for NIH Applications</u> for further direction on which agreements must be submitted for institutional review.

Reminders:

- Have you reviewed ALL your outside activities for those that provide employment, an affiliation, or an appointment through a foreign entity or institution?
- Do any of your foreign appointments, employments, or affiliations provide resources that must be disclosed on your Other Support Page?
 - o Do you have agreements for those resources?
 - If any agreements are in a foreign language, do you have English translations of those agreements?
- Have you reviewed ALL your outside activities involving a foreign entity for any activity that meets the definition of Conducting Research as Part of Consulting (see below)?
 - o Do you have agreements for the research activity?
 - If any agreements are in a foreign language, do you have English translations of those agreements?
- Have you listed ALL resources that are Conducting Research as Part of Consulting on your Other Support page and provided copies of any related agreements for institutional review and attachment?

NIH Other Support (covers all research endeavors, including those outside of Harvard)

Financial Support Disclosures (research awards and other funds)

Funding received through Harvard:

 Review <u>Other Support and Activities</u> report in GMAS for a list of your active and pending grants and incoming billing agreements at Harvard Review PI Dashboard for any internal awards, or make sure to notify your grants manager of any internal award funding if you don't use/have access to the PI Dashboard

Funding received outside of Harvard

- Evaluate all your outside activities (paid and unpaid) to assess whether you have a role on (e.g., commit effort, are named in) or otherwise participate in a research project
- Disclose all funding outside of Harvard, such as grants and external start-up packages. This includes resources made available through joint appointments (e.g., Broad, HMS Affiliated Hospitals, any other non-Harvard institution or entity).
- HHMI Investigators: Reporting individuals who are employed by HHMI and who
 receive general support as HHMI Investigators should report the funding as in the
 following example listed within the Other Resources/Support section of the Harvard
 Other Support template:

HHMI Investigator (PI Last Name) MM/DD/YY - MM/DD/YY Howard Hughes Medical Institute \$1,500,000 DC (\$0 IDC)
HHMI is Dr./Prof. [Last Name]'s employer and funds are not considered grant support. These funds are used to support [general scope of research] in [Last Name]'s lab/group.

Summary:

- In addition to your Harvard grants, are you named on any grants outside of Harvard (investigator, consultant, or other role) or have you committed any effort to grants outside of Harvard (including through outside activities or consulting work, HHMI, or similar awards)?
- Do you have access to any grants, start-up accounts, restricted gifts, or other funds outside of Harvard that support your research endeavors (regardless of where those endeavors take place)?

<u>In-Kind Support</u> Materials/services that are high value and not broadly available to reporting individuals. For example, office/laboratory space, equipment, supplies, data, travel, or coverage of living expenses; also includes employees or students supported by an outside source. This DOES NOT include access to HU core facilities and HU shared equipment or access to any other service center if the terms under which access is granted are the same for the larger research community. Need to add associated time commitment (if applicable) or dollar value (see below). If specific amounts are unknown, provide reasonable estimates.

Research Collaborations and Other Activities

- Review any non-sponsored agreements through Harvard, including data use agreements, collaborations agreement, MTA's, etc., or other engagements through your lab or the University, to assess whether you have received any high value, not broadly available in-kind resources that support your research endeavors.
- Review any personal agreements (agreements directly to you, not Harvard), outside
 activities or other relationships (e.g., outside activities that a researcher participates
 in without written agreement) to assess whether they likewise may govern the
 receipt of these types of resources.

Externally funded trainees, students, or visitors

- Maintain a list of all externally funded personnel in lab that are providing effort towards your research endeavors
- Confer with department administration to compile a list of externally funded students, postdocs, visiting scholars or staff working in your lab or accessing Harvard resources or space as part of a collaboration with your lab.

Summary:

- Have you reviewed ALL your activities for any in-kind resources that are available to you in support of your research endeavors?
- Do you have access to high value, not broadly available materials, data, space, equipment, services, or labor that you are not funding through your Harvard financial resources?
- Do you have any individuals providing effort toward your research endeavors who are not paid directly from your sponsored awards or discretionary funds?

<u>Conducting Research as Part of Consulting</u> Reporting individuals are required to list all domestic and foreign consulting activities deemed to be conducting research. "Conducting research" as defined by Harvard is being a Project Director, Principal Investigator or to otherwise be responsible for the design, conduct or reporting of research regardless of title or position (e.g., an Investigator). This definition does not normally include service on scientific or clinical advisory boards or more general scientific consulting unless it is anticipated that the individual will make a direct and significant intellectual contribution to a specific research project for the entity.

External Consulting Activities involving Research Participation

- Compile a list of all outside activities, appointments, employment, and other relationships (e.g., activities that a researcher participates in without written agreement) to assess whether the activities involve conducting research. Run report in OAIR to assist with review.
- Review the list of outside activities to assess for activities that could be deemed "Conducting Research as Part of Consulting".
- List all foreign AND domestic activities deemed to be Conducting Research as Part of Consulting on your Other Support page.
- Attach written agreements for all consulting activities involving conducting research
 with a foreign entity. Copies must be provided as part of the PDF following the Other
 Support format page, and when necessary, should be translated into English by the
 outside entity/institution or using a freeware translation service (e.g., Google
 Translate) (See above Foreign Appointments).

Summary:

- Will you or have you earned authorship on a publication describing or supporting research under the consulting activity?
- Does the activity involve being responsible for the design, conduct or reporting of research?
- Does the activity involve serving in a fiduciary role for the outside entity or being listed on corporate filing documents?
- If the answer to any of the above is YES, the activity should be included on Other Support.