NIH Disclosure Requirements for Submissions on or after 1/25/22

HMS-HSDM Open Forum
January 20, 2022
Other Support Requirements

• New Other Support form/format required for both JIT and RPPR submissions (form now includes header for in-kind resources)
• New attestation with e-signature of the reporting individual, certifying to the completeness and accuracy of the submitted information

Foreign Contracts and Agreements

• Agreements specific to the individual's appointments, affiliations, and/or employment with a foreign institution must be appended to Other Support as supporting documentation
• Must also include an unredacted, translated version of the agreement if the original is not in English
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.

Signature & Date: _____________________

**IMPORTANT NOTE:** Signature authority cannot be delegated to anyone, including Grant Managers and Administrators.

The reporting PI/key personnel must sign their Other Support after all required documentation has been attached, and after it’s been reviewed by their school’s submitting office, prior to submission to NIH.

**TIP:** Key Personnel should review the e-signature instructions on the OVPR website [How to "Electronically Sign a PDF" (PDF)] and create a saved certificate *in advance*, as this could be time-consuming if they need help.
**NIH High-Level Process Overview**

**Proposal Submission**
- Submit proposal following new Biosketch guidelines

**Foreign Agreements Review**
- Upload foreign agreements to the person's Outside contracts and agreements doc repository in GMAS (refer to [job aid](#))
- *This can be completed any time there is a new agreement to be reviewed regardless of lifecycle phase*

**Just In Time Request**
- Enter JIT request in GMAS and upload OS documents for all Key Personnel and any other required information. Route to central office by deadline

**Just In Time Review**
- Central reviewers will review the JIT request in GMAS and ensure agreements that need to be included are attached. Once the review is complete the central reviewer will request OS with e-signatures

**Just In Time Submission**
- GM’s will obtain signatures for all Key Personnel on Other Support. Upload complete package under JIT request in GMAS. Central office flattens signature and uploads the flattened version to eRA Commons

**Reminder**: NIH requires notification, within 30 days, of any previously undisclosed support.
**NIH Proposal Submission**

<table>
<thead>
<tr>
<th>Role</th>
<th>Task</th>
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<tbody>
<tr>
<td>Key Personnel</td>
<td>Complete Biosketch following new guidelines for sections A, B and D</td>
</tr>
<tr>
<td>GM</td>
<td>Review for adherence to NIH administrative requirements and submit to Central Office for Review</td>
</tr>
<tr>
<td>Central Office Reviewer</td>
<td>Review, sign off as AOR and submit to NIH via ASSIST</td>
</tr>
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Foreign Agreements Review

Proposal Submission

Foreign Agreements Review

Just-In-Time Request

Just In Time Review

Just In Time Submission

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<tr>
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<tr>
<td>Key Personnel</td>
<td>In GMAS, upload (or provide a copy to your GM to upload) all relevant foreign agreements to their Person Profile (see Outside Foreign Contracts and Agreements). Remember to upload the original and an unredacted, translated copy</td>
</tr>
<tr>
<td>School Central Reviewer (SCR)</td>
<td>When the SCR receives an email that a new agreement has been uploaded, the SCR will review the agreement and change the status to:</td>
</tr>
<tr>
<td></td>
<td>• <strong>Review in process</strong> indicates that review has started. SCR may reach out to the Key Personnel for additional information to facilitate review.</td>
</tr>
<tr>
<td></td>
<td>• <strong>Reviewed: OK to submit</strong> indicates that review is complete and the agreement should be attached to Other Support prior to submission to NIH</td>
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<tr>
<td></td>
<td>• <strong>Reviewed: Not for submission</strong> indicates that review is complete, but the document should not be submitted (usually because it does not meet the federal standard for disclosure; your SCR will reach out with an explanation)</td>
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### JIT Request including Other Support

#### Proposal Submission

#### Foreign Agreements Review

#### Just-In-Time Request

#### Just In Time Review

#### Just In Time Submission

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<tr>
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<tbody>
<tr>
<td>Central Office</td>
<td>When HMS is prime, forward JIT email request from NIH GMS to PI, Grants Manager, and Central Reviewer (AOR)</td>
</tr>
<tr>
<td>Key Personnel</td>
<td>Review GMAS &quot;Other support and activities&quot; report; provide all sources of research support (from GMAS report and elsewhere) to GM to update Other Support document</td>
</tr>
<tr>
<td>GM</td>
<td>Update Other Support and review to ensure it meets NIH formatting and content requirements; enter JIT request* in GMAS (when we are prime or sub under NIH award) and upload Other Support for all key personnel</td>
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*Just-In-Time Request Job Aid*
### JIT Review

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<tbody>
<tr>
<td>Central Office</td>
<td>Review JIT request in GMAS, coordinate any changes with GM. Once review is complete, put together a complete package including supporting documentation for foreign agreements to be submitted. Request GM obtain e-signatures on all Other Support.</td>
</tr>
<tr>
<td>Key Personnel</td>
<td>Review and electronically sign Other Support attesting to completeness and accuracy</td>
</tr>
<tr>
<td>GM</td>
<td>Work with central office reviewer to finalize JIT request by updating any documents that need changes, obtaining e-signatures on Other Support for all Key Personnel and upload a finalized signed package in GMAS for the JIT request</td>
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### JIT Submission

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<tbody>
<tr>
<td>Central Office</td>
<td>• Combine and flatten the final, signed version of documents to be submitted to NIH for the JIT request.</td>
</tr>
<tr>
<td></td>
<td>• Upload the flattened version to eRA Commons JIT module</td>
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<tr>
<td></td>
<td>• Enter IACUC/IRB dates (if required)</td>
</tr>
<tr>
<td></td>
<td>• Submit JIT in eRA Commons</td>
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*Do not delete the unflattened version from the GMAS JIT Request*
RPPR Review and Submission

- As with JIT, all RPPRs where HMS is the prime awardee or a subrecipient under and NIH prime award must be entered into GMAS (as a Continuation request) for central review prior to submission.

- GMs must upload any Harvard Other Support docs being submitted with the RPPR (i.e., for any new key personnel, or for changes to the support of existing key personnel).
  - **Part-of accounts**: if Other Support is being submitted for Harvard key personnel who are in other tubs (not HMS/HSDM), work with the individual’s GM to make sure their Other Support has been reviewed and approved first by their department and central offices.
  - When HMS is a subrecipient, GM should also upload any documentation required by the prime institution.
Subaward Questions

Harvard is the subrecipient and the prime sponsor is NIH:

• For any proposal on which Harvard is a subrecipient and the prime sponsor is NIH, the GM will need to create a JIT/Continuation (RPPR) request in GMAS and follow the same process as if it were an award directly to Harvard

Harvard is the prime recipient of an NIH award and that includes subawards:

• Harvard expects the subrecipient organization to have reviewed and obtained appropriate institutional review and Key Personnel signature on any Other Support documentation submitted to Harvard
• Ensure that any documents received from the subrecipient are unlocked/unsecured, or already flattened (preferred), prior to submission to Harvard
• (Note that we follow the same processes for part-of accounts within Harvard: the department and central office of the part-of account key personnel should review, sign and flatten their Other Support before sending to us when HMS owns the prime award)
GMAS System Enhancements and New Features
New GMAS request type, Just-In-Time (JIT):

- When the JIT email from NIH GMS is received, enter a Just-in-Time GMAS request in the pending segment (Just-In-Time Request Job Aid).
- Upload Other Support docs for all key personnel and lock and route request for review.
Outside Foreign Contracts and Agreements
System Enhancements

• An “Outside foreign contracts and agreements” document repository is available for every person profile in GMAS.

• You can upload unreviewed contracts/agreements to the doc repository.

• A notification will go to the appropriate reviewer that a document is pending review.

• The reviewer will update the document category to reflect the review status.

• For additional details, refer to Outside Foreign Contracts and Agreements.
Key Takeaways: GM Responsibilities

All NIH and NSF PI’s and Senior/Key Personnel were required to complete the HTP module and acknowledge they have been advised of the regulatory changes affecting disclosures.

The PI/Key Personnel is responsible for providing all research support information to their grants administrator or updating their own Other Support/Current & Pending Support. The consolidated report in GMAS can assist with this effort but does not take the place of the reporting individual's complete disclosure of all resources and support, some of which will not appear on the GMAS report.

The Key responsibility of the Grant Manager is to (1) Create JIT/Continuation request in GMAS (2) Assist PI/Key Personnel with completing their Other Support and Biosketch (3) upload documents to JIT/Continuation request and assist PI with upload, as needed, of any foreign agreements for review (4) facilitate obtaining signatures for Key Personnel.

Each school has a school reviewer to help faculty determine if an agreement needs to be disclosed.

The PI/Key Personnel is required to electronically sign their own Other Support attesting to the completeness and accuracy of the information on the document.
Resources Available Now on the **OVPR Website**

- [Other Support FAQs](#), Harvard [Template](#) and [Guide](#)
- HTP course *“Disclosing Other Support: Guidance for Faculty & Key Personnel”*
- Instructions for Key Personnel on *“How to Electronically Sign a PDF”*

And more!
Contacts

Foreign Contract and Agreement Review and Questions
international_collaborations@hms.harvard.edu
Lindsay Monahan

General Other Support & Biosketch Questions
Contact your pre-award ORA rep
Other Questions?