

Federal Sponsor Other Support & International Engagements: What You Need to Know

David Mulder

U-M Medical School Office of Regulatory Affairs
Assistant Director - Conflicts of Interest & Outside Interests

davemuld@umich.edu

April Pepperdine

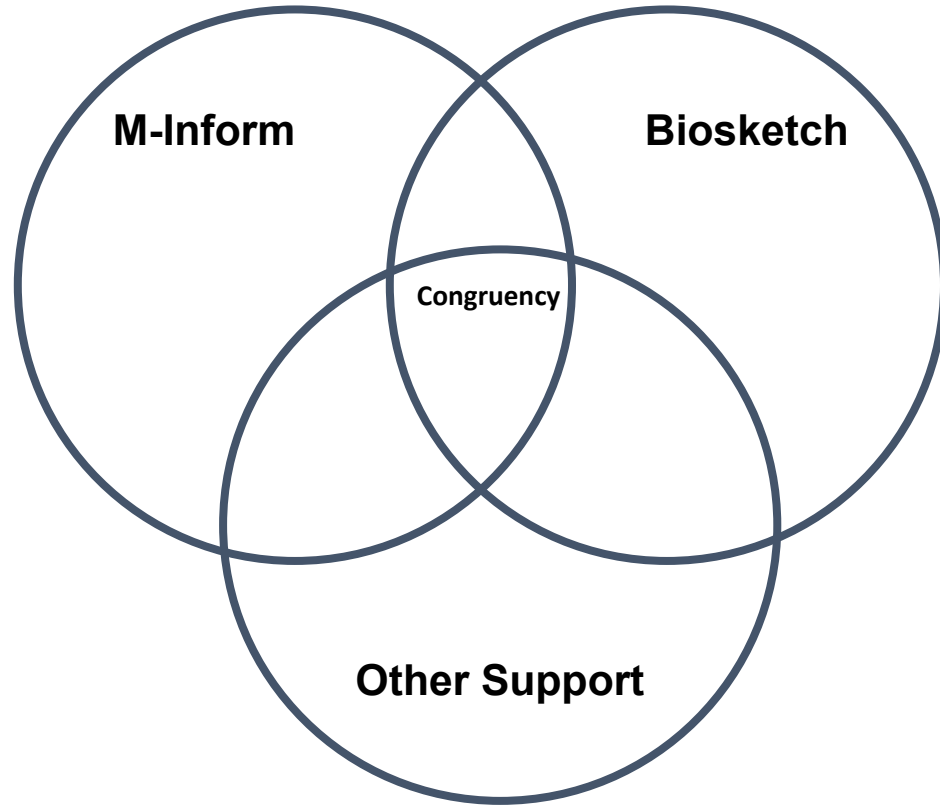
U-M Office of Research Conflict of Interest Director

apepperd@umich.edu

March 24, 2022

Topics

- Background/Context
- M-Inform Disclosures
- Biosketches
- Other Support
- Scenarios
- How RAs can help
- Central Office Review
- Foreign Components
- Non-NIH Sponsors
- Future
- Help/Resources



Reporting Activities to Federal Sponsors

- Increased scrutiny of sources of support, institutional affiliations, and international collaborations related to sponsor-funded projects.
- Additional policies and heightened expectations for investigators and institutions.
- NIH first [reminded](#) institutions of expectations regarding Foreign Components and Other Support in July 2019.
- NIH then implemented [new requirements](#) for Biosketches and Other Support, provided to NIH on or after 1/25/2022.

Disclosing Activities External to U-M

- Outside Activities need to be disclosed in M-Inform.
 - Investigators involved in NIH-sponsored activities (current or future) are required to upload supporting documentation for international activities in M-Inform.
 - Both original and English translation (if necessary)
 - Examples include:
 - Contract
 - Written agreement
 - Research proposal

Biosketch

- **Template (including format) has changed** - make sure investigators are using the most up-to-date version
- **Most significant change — Section B: Positions, Scientific Appointments, and Honors**
 - List in **reverse** chronological order **all** current positions and scientific appointments both domestic and foreign. Include:
 - All affiliations with entities or governments outside the United States
 - All titled academic, professional, or institutional appointments
 - whether or not remuneration is received
 - whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary)
- Consider using [SciENCv](#) to generate the Biosketch

Other Support

- **Other Support:** Any resources available to support any of an investigator's research endeavors
- Disclose ALL active and pending sources of Other Support
- **NIH Other Support now in two sections:**
 - Projects/proposals
 - In-kind (non-financial) resources

Other Support: Projects/Proposals

- **Projects/proposals, includes:**
 - U-M projects, including those routed through ORSP, internally funded, etc.
 - Projects not routed through U-M or conducted as part of a non-UM appointment
 - Formal external **consulting** arrangements that involves the design, conduct, or reporting of research
 - Examples include:
 - Work that may result in publication in an academic journal
 - Designing a protocol
 - Data analysis
 - Serving on a steering committee for a clinical trial

Other Support: In-Kind Support

- In-kind resources that meet [certain criteria](#) must be included in Other Support
- In-kind resources can be a person, place, or thing
- In-kind resources include, but are not limited to:
 - Personnel (e.g., visiting scholars, visiting students, supported by a non-UM entity)
 - Space (e.g., office space, lab space)
 - Equipment
 - Materials
 - Supplies

Other Support: In-Kind Support

- **Disclose in-kind** (i.e., non-monetary) resources that meet all the following criteria:
 - Are not publicly/widely available, and
 - Were, or will be, provided by a non-UM entity (either domestic or foreign), and
 - Were provided in the past three years (for active in-kind resources)

Note: In-kind resources intended for use on the proposed project should be included as part of the 'Facilities and Other Resources' or 'Equipment' section of the application and not 'Other Support'

Other Support: Format

- The revised NIH Other Support format does **not** include separate sections for:
 - Foreign Components
 - Foreign Appointments/Affiliations
 - Foreign Collaborations
 - Visitors

Note: Appointment/Affiliation, collaboration, and/or visitor information *may* need to be included as part of an individual entry for a project/proposal or in-kind resource

Other Support: Supporting Documents

- For sources of Other Support that are not routed through U-M and are with an entity outside the U.S., provide **supporting documentation**
- Documents should be submitted in their original language and, if applicable, with an English-language translation

Examples include, but are not limited to:

- Contracts
 - Grants
 - Any other agreements specific to appointments, affiliations, and/or employment with an institution or entity outside the U.S.
- Machine translations (e.g., Google translate) are acceptable
 - Reminder: NIH investigators can refer to M-Inform for copies of their contracts

Other Support: Electronic Signatures

- **Electronically sign** your Other Support document
 - U-M recommends using the [SignNow](#) e-signature service
 - A typed name is **not** a digital signature and is not acceptable
 - Scanned ink signatures are **not** acceptable (unless they are included as part of a digital signature like SignNow)

Scenarios



- The following 6 scenarios present situations when a hypothetical U-M investigator, Dr. Patel, might need to include an activity in her Other Support document for NIH and, if necessary, provide supporting documents.
- Consider each scenario and use the Zoom “Polling” feature to answer the questions presented.

**Please refer to the Scenarios document for the answers / examples used in this session.*

Scenario 1



Dr. Chen, from Fudan University in China, has written a letter of support for Dr. Patel's R01 renewal. The letter states:

Dear Dr. Patel,

I write to confirm my enthusiastic support of your NIH R01 competing grant renewal application entitled, "Genetic and Molecular Analysis of Abhorrentius Deletrius." As you know, we recently determined that human cells containing a mutation in the RAD-123 line are severely compromised for human HeLa cells and XYZ-deficient hamster cells. We look forward to learning the results of your proposed experiments. Indeed, I think your experimental plan provides a logical path forward to test how interactions between RAD-123 and BAD-321 facilitate cellular retrotransposition. In sum, I find your project exciting and I look forward to our continued interactions and learning the results of your proposed studies.

With Best Regards,

Dr. Li Chen

Questions:

- Does Dr. Patel need to include Dr. Chen's letter in her Other Support document?
- What if their roles were reversed?

Scenario 2

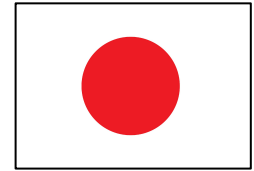


Dr. Patel is the PI on a clinical trial sponsored by GutenPharma in Germany. The contract can be found by going to AWD012345 in eRPM.

Questions:

- Does Dr. Patel need to include the GutenPharma trial in her Other Support document?
- If yes, does she need to provide “Supporting Documents” to NIH with her Other Support (e.g., an English-language copy of the contract)?

Scenario 3



Dr. Patel has a visiting scholar, Dr. Sato from the University of Tokyo, working in her lab. Dr. Sato is contributing on two U-M internally funded research projects that Dr. Patel is currently working on. Dr. Sato is supported 100% by the University of Tokyo.

Questions:

- Does Dr. Patel need to include Dr. Sato on her Other Support document?
- If yes, does she need to provide “Supporting Documents” to NIH with her Other Support (e.g., an English-language copy of the agreement)?

Scenario 4



Dr. Patel has a consulting agreement with DrogueFantastique in France. She's overseeing the protocol design of their upcoming clinical trial for a new drug.

Questions:

- Does Dr. Patel need to include the DrogueFantastique trial in her Other Support document?
- If yes, does she need to provide “Supporting Documents” to NIH with her Other Support (e.g., an English-language copy of the contract)?

Scenario 5



Dr. Patel has a consulting agreement with Pfizer.
She's overseeing the protocol design of their upcoming clinical trial for a new drug.

Questions:

- Does Dr. Patel need to include the Pfizer trial in her Other Support document?
- If yes, does she need to provide “Supporting Documents” to NIH with her Other Support (e.g., an English-language copy of the contract)?

Scenario 6



Dr. Patel has a Dutch doctoral student, Bram Meijer, working in her lab on his dissertation. He is making use of Dr. Patel's facilities, equipment, supplies, personnel, etc. Bram is supported 100% by the University of Amsterdam.

Questions:

- Does Dr. Patel need to include Bram on her Other Support document?
- If yes, does she need to provide "Supporting Documents" to NIH with her Other Support (e.g., an English-language copy of the agreement)?

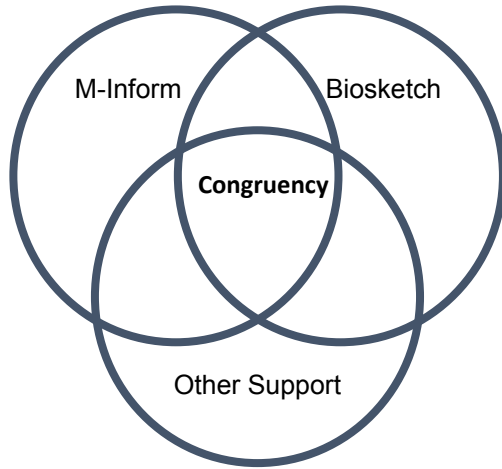
How RAs Can Help

- Familiarize yourself with the most recent sponsor requirements, and be on the lookout for additional changes
- Ensure the following:
 - Correct sponsor format is used, including [overlap](#) statement(s)
 - If none exist, state: “None of the active/pending projects listed above represents an overlap of science, budget, or committed effort.”
 - Electronic signature is completed, as required
 - [Flatten](#) Other Support PDFs after signature to meet file size limit
 - Supporting documentation is included in Other Support, as needed

Central Office Other Support Review

- **ORSP Staff will review all Other Support and Current & Pending Support for:**
 - No expired projects in “Active” section
 - No investigator reports more than 12 Calendar Months of effort
 - Completed “Overlap” statement(s)
 - Investigator signatures
 - Compliance with sponsor formatting requirements

Central Office Other Support Review



- **COI Office Staff will review Sponsor Documentation (e.g., biosketch, Other Support, Current & Pending Support) and M-Inform Disclosures at JIT/Award for NIH investigators who:**
 - Answered “yes” to one or more of the International Engagement questions in the “Sign PAF” activity **or**
 - Disclosed an international activity in M-Inform

Other Support Review: Possible Outcomes

- No changes required
- Communication with investigators for additional information regarding nature of international activities
- Communication with investigators and/or RA(s) to make any necessary updates to sponsor documentation including supporting documents
- Submission of revised Other Support/Current & Pending documentation to Federal sponsors if required

Throughout the Award

- **New Sources of active Other Support** (not pending) should be reported in the annual Research Performance Progress Report (RPPR)
- **Previously undisclosed** sources of Other Support that should have been reported at JIT or in the RPPR, but were not, need to be reported to NIH within 30 days



Contact Other.Support.Questions@umich.edu **immediately** if you become aware of previously undisclosed Other Support

Foreign Components

NIH definition: The existence of any **significant scientific element** or segment of an NIH-funded (or proposed) project outside of the United States

- It **doesn't matter** if NIH funds are being used
- Based on **location** of the work being performed

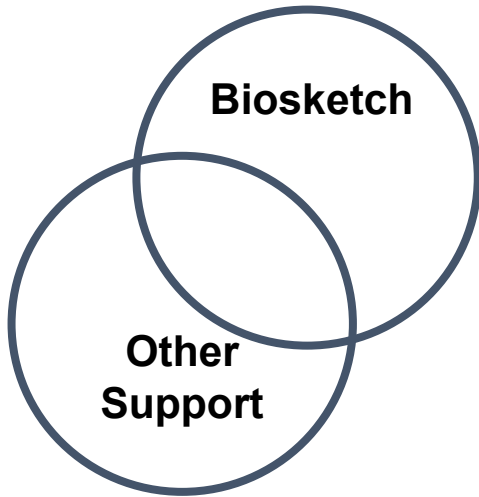
Examples of work that *might* constitute a “significant scientific element” include:

- Involvement of human subjects or animals at a foreign location
- Extensive foreign travel by recipient project staff for the purpose of data collection, surveying, or sampling
- Collaborations with investigators at a foreign site anticipated to result in co-authorship
- Use of facilities or instrumentation at a foreign site
- Generally, the “Specific Aims” portion of the proposal can be a guide

Foreign Components

- **Prior** approval from NIH is required
 - During proposal process:
 - Answer “yes” to PAF question 5.13
 - Answer “yes” to SF424 R&R (Other Project Information) questions 6, 6.a, 6.b
 - After the project is awarded:
 - Submit an Award Change Request (ACR) via eRPM
- Do not include Foreign Components in Other Support

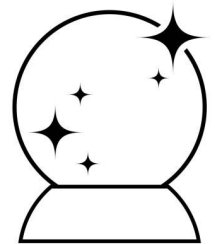
And Now, a Word from our Other Sponsors



- Generally, if you're in compliance with NIH's requirements, you will be compliant with other sponsors (e.g., NSF)
However:
 - Only NIH currently requires "supporting documentation" (e.g., contracts, agreements)
 - Only NIH currently requires electronic signature
 - NSF requires overlap statements for each project
 - DARPA recently released a [risk-based measure](#) to assess potential undue foreign influence conflicts of interest/conflicts of commitment - see their [FAQ](#) and a recent [summary](#) from Ropes & Gray for more info
 - Consult the U-M [Disclosure Matrix](#) for additional sponsor-specific nuances

What Does the Future Hold...?

- International Engagement landscape is still very much in flux
- National Security Presidential Memorandum 33 ([NSPM-33](#)) was issued at the end of the Trump administration
 - Office of Science & Technology Policy (OSTP) released [guidance](#) to Federal agencies for implementation of NSPM-33 in January 2022
 - 90-day comment period; 120 days for OSTP to finalize
 - We expect the most change from agencies *other* than NIH and NSF
- Current events don't stop happening (e.g., Ukraine)



Help!

COI staff - COI.Support@umich.edu

- M-Inform disclosures
- Ongoing one-on-one consultations
- Office hours during July disclosure period
- General questions about outside interests/potential conflicts of interest

Other Support Review Team - Other.Support.Questions@umich.edu

- Initial proposal submissions (i.e., Biosketches, Foreign Components)
- JIT Materials:
 - Other Support
 - Supporting documentation
- Progress reports (RPPRs)
- Previously undisclosed Other Support

When in doubt: Disclose/Report!

When in doubt: Reach out! Either email address or office can help connect you to the right resources.

Resources

- ★ [Disclosure Matrix](#) shows what to disclose in Other Support and M-Inform
- ★ Outside Activity Disclosure [Guidance](#)
- [NIH Other Support Reporting](#) and [Biosketch](#) web pages, including:
 - [Checklist for NIH Biosketches, Other Support, and RPPRs](#)
 - [Other Support Template](#)
 - [Common Other Support Examples](#) - including Joint Institute
- [NSF Current & Pending Support and Biosketch](#) web page
- Medical School [Other Support Resources](#) web page
- New [Other Support Review Process](#) web page
- Email questions to Other.Support.Questions@umich.edu for sponsor documentation or COI.Support@umich.edu for M-Inform disclosures

Questions



Closing

Thank you!

For questions or assistance related to this topic, contact:

Other.Support.Questions@umich.edu

For questions about Navigate webinars and professional development training offerings, contact the Navigate Team at

navigate-research@umich.edu