



National Institute of Environmental Health Sciences  
*Your Environment. Your Health.*

# **Business Break-Out Session Worker Training Program Meeting**

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**October 24, 2018**

## Agenda

- Deadlines Reminder
- Closeout
- Consultants and Consortia
- Research Integrity



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## Deadlines Reminder

	HWWTP U45s (8/1 starts)	DOE UH4s (9/1 starts)	IDR UH4s (6/1 starts)
Federal Financial Report (FFR)	12/31/2018	12/31/2018	9/30/2019*
Carryover Request	3/1/2019	3/1/2019	12/1/2018
Progress Report (RPPR)	6/1/2019	7/1/2019	9/30/2019*

\*Due dates for final reports assume no no-cost extension requests.

- Failure to submit complete, accurate, and timely reports may indicate the need for closer monitoring by NIH or may result in possible award delays or enforcement actions.

# Closeout

- Closeout documents are due 120 days after the project period end date.
- Closeout documents include:
  - Final Federal Financial Report (FFR)
  - Final Research Performance Progress Report (FRPPR)
  - Final Invention Statement (FIS) (not required for U45s or UH4s\*)

## Final Federal Financial Report

- Similar to the Annual FFR, but cannot include unliquidated obligations.
- It is very critical that the expenditures reported on the Final FFR are consistent with the last quarterly Cash Transaction Report in the Payment Management System. A mismatch may result in a federal debt collection notice!



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## Final Research Performance Progress Report (FRPPR)

- Similar to the Annual RPPR, but includes “Section I. Outcomes”.
- Whatever you put in the Outcomes Section will go on the NIH public website, so please review for accuracy/completeness.
- “FRPPR” vs. “IRPPR”
  - If you’ve submitted a Type 2 continuation application, the report will be called an “Interim” RPPR, or IRPPR.
  - The FRPPR and IRPPR are the same form.
  - If your Type 2 does not get funded, your IRPPR becomes an FRPPR in our system automatically.

## SBIR Lifecycle Certification

- A certification is required at the following times:
  - For SBIR Phase I Awardees: At the time of receiving final payment or disbursement from the Payment Management System or via contract.
  - For SBIR Phase II Awardees: prior to receiving more than 50% of the total award amount and prior to final payment or disbursement from the Payment Management System or via contract.
- The Life Cycle Certification ~~does not get sent to NIH~~, but must be kept in the grant files, and be made available upon request (e.g. audit).

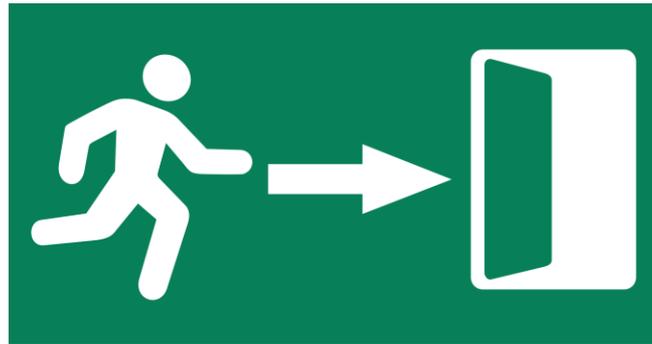
UPDATE! Effective 1/1/2019, Lifecycle Certifications must be sent to NIH as an attachment to question G.1 of the FRPPR. See NOT-OD-19-025 for details.

## What if you're not ready to closeout?

- Most institutions may authorize a no-cost extension of the final budget period, up to 12 months.
  - Notifications need to be submitted through the eRA Commons prior to the end of the current project period. (The link to submit becomes available 90 days before the project end date).
  - In the notification, the organization must certify:
    - There is additional work to be done on the existing project scope.
    - There are funds remaining in the grant to do the additional work.
- If you miss the eRA Commons link, a prior approval request can be submitted to NIEHS.

## For More Information on Closeout:

- See Section III of your Notice of Award.
- NIH Resource Page:  
<https://grants.nih.gov/grants/closeout/index.htm>
- NIH Forms and Instructions Library:  
<https://grants.nih.gov/grants/forms/all-forms-and-formats.htm>





# Special Policy Topic: Consortia vs. Consultants



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# The Question:

 Send	To...	Molly @ NIEHS
	Cc...	
	Subject	Rebudgeting on our WTP grant

Dear Molly,

For our HazMat Training Grant, we work with Organization Y, which provides trainers and space for us to conduct trainings. In the past, they have been a consortium, but we think maybe they're consultants. Can we rebudget funds from consortia to consultants for Organization Y?

Best wishes,  
AOR/SO

# Definitions from the NIH Grants Policy Statement

- Consortium agreement

- A formalized agreement whereby a research project is carried out by the recipient and one or more other organizations that are separate legal entities. **Under the agreement, the recipient must perform a substantive role in the conduct of the planned research** and not merely serve as a conduit of funds to another party or parties. **These agreements typically involve a specific level of effort from the consortium organization's PD/PI** and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including F&A costs. The relationship between the recipient and the collaborating organizations is considered a subaward relationship. (See Consortium Agreements chapter in IIB).

- Consultant

- An individual who provides **professional advice or services for a fee**, but normally not as an employee of the engaging party. In unusual situations, an individual may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee. To prevent apparent or actual conflicts of interest, recipients and consultants must establish written guidelines indicating the conditions of payment of consulting fees. **Consultants also include firms that provide professional advice or services.** (See Cost Considerations—Allowability of Costs/Activities—Selected Items of Cost—Consultant Services).

## Definitions from Uniform Grants Guidance (45 CFR 75.351) (Part 1)

- (a) **Subrecipients.** A subaward is for the purpose of carrying out a portion of a Federal award and **creates a Federal assistance relationship** with the subrecipient. See § 75.2 Subaward. **Characteristics which support the classification of the non-Federal entity as a subrecipient include when the non-Federal entity:**
  - (1) Determines who is eligible to receive what Federal assistance;
  - (2) Has its performance measured in relation to whether objectives of a Federal program were met;
  - (3) Has responsibility for programmatic decision making;
  - (4) Is responsible for adherence to applicable Federal program requirements specified in the Federal award; and
  - (5) In accordance with its agreement, uses the Federal funds to carry out a program for a public purpose specified in authorizing statute, as opposed to providing goods or services for the benefit of the pass-through entity.

## Definitions from Uniform Grants Guidance (45 CFR 75.351) (Part 2)

- (b)**Contractors.** A contract is for the purpose of obtaining goods and services for the non-Federal entity's own use and **creates a procurement relationship** with the contractor. See § 75.2Contract. **Characteristics indicative of a procurement relationship between the non-Federal entity and a contractor are when the contractor:**
  - (1) Provides the goods and services within normal business operations;
  - (2) Provides similar goods or services to many different purchasers;
  - (3) Normally operates in a competitive environment;
  - (4) Provides goods or services that are ancillary to the operation of the Federal program; and
  - (5) Is not subject to compliance requirements of the Federal program as a result of the agreement, though similar requirements may apply for other reasons.

## Definitions from Uniform Grants Guidance (45 CFR 75.351) (Part 3)

- (c) **Use of judgment in making determination.** In determining whether an agreement between a pass-through entity and another non-Federal entity casts the latter as a subrecipient or a contractor, **the substance of the relationship is more important than the form of the agreement.** All of the characteristics listed above may not be present in all cases, and the pass-through entity must use judgment in classifying each agreement as a subaward or a procurement contract.

## Some helpful questions to ask:

- What is the scope of work being considered?
- Is Organization Y performing routine services?
- Is Organization Y substantially involved in the planning activities?
- Does someone at Organization Y have a key personnel role (with committed effort) on this project?



## Consultants:

- Procurement rules apply!
- This includes:
  - Competition procedures.
  - Cost / Price analysis may need to be conducted, depending on the cost threshold.
  - Written contracts must exist, including all applicable Contract Terms found in 45 CFR 75 Appendix II.



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## Consortia

- Federal assistance rules apply!
- This includes:
  - All requirements in 45 CFR 75.352 Requirements for Pass-through entities.
  - All requirements in Section 15 of the NIH Grants Policy Statement.



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## Consortia

- NIH requires a written agreement be established **prior to entering** into a consortium.
- Although NIH does not dictate the terms of the agreement, NIH does require a minimum list of topics that should be covered in the written agreement. (See [NIH Grants Policy Statement, Section 15.2.1.](#))



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# Requirements for the Written Agreement

- Who?
  - Identification of the individual who will serve as the consortium lead investigator and other individuals responsible for the research activity at each consortium participant along with their roles and responsibilities.
  - When multiple PD/PIs are involved at different organizations, any consortium agreement must address the unique aspects to these individuals holding the PD/PI role including the requirement for the prime institution to secure and retain all PD/PI signatures for all applications, progress reports, and post-award prior approval requests. Further, such signatures must be made available to NIH or other authorized DHHS or Federal officials upon request.

## Requirements for the Written Agreement

- What about the Money?
  - Procedures to be followed in reimbursing each consortium participant for its effort, including dollar ceiling, method and schedule of reimbursement, type of supporting documentation required, procedures for review and approval of expenditures of grant funds at each organization and timing of applicable reporting requirements.
  - If different from those of the recipient, a determination of policies to be followed in such areas as travel reimbursement and salaries and fringe benefits (the policies of the consortium participant may be used as long as they meet NIH requirements).

## Requirements for the Written Agreement

- How about Policies?
  - Terms that establish whether the Financial Conflict of Interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators. Regardless of which policy applies, terms should describe the implementation.
  - Provisions regarding property (other than intellectual property), program income, publications, reporting, and audit necessary for the recipient to fulfill its obligations to NIH.
  - Incorporation of applicable public policy requirements and provisions indicating the intent of each consortium participant to comply, including submission of applicable assurances and certifications.

## Requirements for the Written Agreement

- What about Sharing?
  - A provision addressing ownership and disposition of data produced under the consortium agreement.
  - A provision making the NIH data sharing and inventions and patent policy, including a requirement to report inventions to the recipient, applicable to each consortium participant and its employees in order to ensure that the rights of the parties to the consortium agreement are protected and that the recipient can fulfill its responsibilities to NIH.
  - Expectations for authorship and co-authorship on publications.

## Requirements for the Written Agreement

- What about Reporting?
  - Procedures for directing and monitoring the research effort.
  - Provisions regarding compliance with requirements for a DUNS number and subrecipient reporting under FFATA. Note, the recipient must provide the FAIN to all subrecipients to aid in this requirement.

## Take Home Messages:

- Decide the scope of work first!
- Be clear about what the relationship is, so you know what rules apply.
- Regardless of which route you go, get a written agreement in place.



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National Institute of Environmental Health Sciences  
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# Special Policy Topic: Preserving the Integrity of Research



# Letter from Francis Collins to NIH Recipient Community, August 20, 2018



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health  
Bethesda, Maryland 20892

August 20, 2018

Dear Colleagues:

For many decades, the National Institutes of Health (NIH) and institutions like yours have participated in productive partnerships that greatly advance biomedical science. Scientists at universities and academic medical centers, supported by NIH, have made seminal biomedical discoveries that have led to dramatic improvements in human health. The scientists whose work NIH is proud to help support come from all over this country and the world, bringing rich, diverse perspectives and backgrounds to the biomedical research enterprise.

The NIH-funded biomedical enterprise depends on a competitive system, which, to be successful, must be fair, transparent, and trustworthy.

Unfortunately, threats to the integrity of U.S. biomedical research exist. NIH is aware that some foreign entities have mounted systematic programs to influence NIH researchers and peer reviewers and to take advantage of the long tradition of trust, fairness, and excellence of NIH-supported research activities. This kind of inappropriate influence is not limited to biomedical research; it has been a significant issue for defense and energy research for some time. Three areas of concern have emerged:

1. Diversion of intellectual property (IP) in grant applications or produced by NIH-supported biomedical research to other entities, including other countries;
2. Sharing of confidential information on grant applications by NIH peer reviewers with others, including foreign entities, or otherwise attempting to influence funding decisions; and
3. Failure by some researchers working at NIH-funded institutions in the U.S. to disclose substantial resources from other organizations, including foreign governments, which threatens to distort decisions about the appropriate use of NIH funds.

NIH is working with other government agencies and the broader biomedical research community, including NIH-funded institutions and U.S. university professional organizations, to identify steps that can help mitigate these unacceptable breaches of trust and confidentiality that undermine the integrity of U.S. biomedical research.

These efforts will be supported by a working group of the Advisory Committee to the (NIH) Director that will tap experts in academic research and security to develop robust methods to:

1. Improve accurate reporting of all sources of research support, financial interests, and relevant affiliations;

Page 2

2. Mitigate the risk to IP security while continuing NIH's long tradition of collaborations with foreign scientists and institutions; and
3. Explore additional steps to protect the integrity of peer review.

Concurrent with these efforts, we are using this opportunity to reach out to you for your help. We recently reminded the community<sup>1</sup> that applicants and awardees must disclose all forms of other support and financial interests, including support coming from foreign governments or other foreign entities. We therefore expect you to work with your faculty and with your administrative staff to make sure that, in accordance with the NIH Grants Policy Statement,<sup>2</sup> all applications and progress reports include all sources of research support, financial interests, and relevant affiliations.

In addition, in the weeks and months ahead you may be hearing from our Office of Extramural Research (OER) regarding grant administration or oversight questions or requests about specific applications, progress reports, policies, or personnel from, or affecting, your institution. We also expect and encourage your institution to notify us immediately upon identifying new information that affects your institution's applications or awards. Lastly, we encourage you to reach out to an FBI field office to schedule a briefing on this matter. We greatly appreciate your willingness to work closely with OER to address these ongoing concerns.

We thank you in advance for working with us on this serious matter. Should you have questions, please send them to [grantsinfo@od.nih.gov](mailto:grantsinfo@od.nih.gov).

Sincerely yours,

Francis S. Collins, M.D., Ph.D.  
Director, NIH

## Areas of Concern:

- Protection of Intellectual Property disclosed in NIH grant applications or produced by NIH-supported activities.
- Unallowable sharing of confidential information on grant applications by NIH peer reviewers with others.
- Failure to report Other Support from other organizations, which threatens to distort the decisions about the appropriate use of NIH funds.

## What does NIH want you to do?

- 1) Make sure your Financial Conflicts of Interests policies are up to date and being applied correctly.
  - NIH recently published a reminder Guide Notice for requirements to report FCOIs- [NOT-OD-18-160](#)
  - NIH Resource Page for FCOI policies: <https://grants.nih.gov/grants/policy/coi/index.htm>



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## What does NIH want you to do?

### 2) Provide complete reports.

- Applications need to include all personnel and collaborating institutions, so our Scientific Review Officers can manage for conflicts.
  - Biosketches should include all organizational affiliations.
- Progress Reports need to include complete All Personnel Reports, so our Program / Grants Management staff can manage for conflicts.
  - Any individual with > 1 month of effort on the grant should be reported.
- Listing eRA Commons IDs on Biosketches and Key Personnel Reports helps us link people or tell people apart!

# What does NIH want you to do?

- 3) Be aware of how to report concerns.
  - See Section II of your Notice of Award.
  - For general NIH policy questions on Intellectual Property, Financial Conflict of Interest, etc.:  
<https://grants.nih.gov/support/index.html>
  - For resources on Research Integrity, see HHS Office of Research Integrity: <https://ori.hhs.gov/>
  - Let us know if you have questions!





**Thank you!**  
**Any questions?**