



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

PEPH Webinar: Grants Management Tips for Community Organizations

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Partnerships for Environmental Public Health (PEPH) is about engaging diverse communities to address current environmental health research needs.

To be successful, community groups need access to scientific and administrative capabilities to manage their research projects.



Purpose of the Webinar:

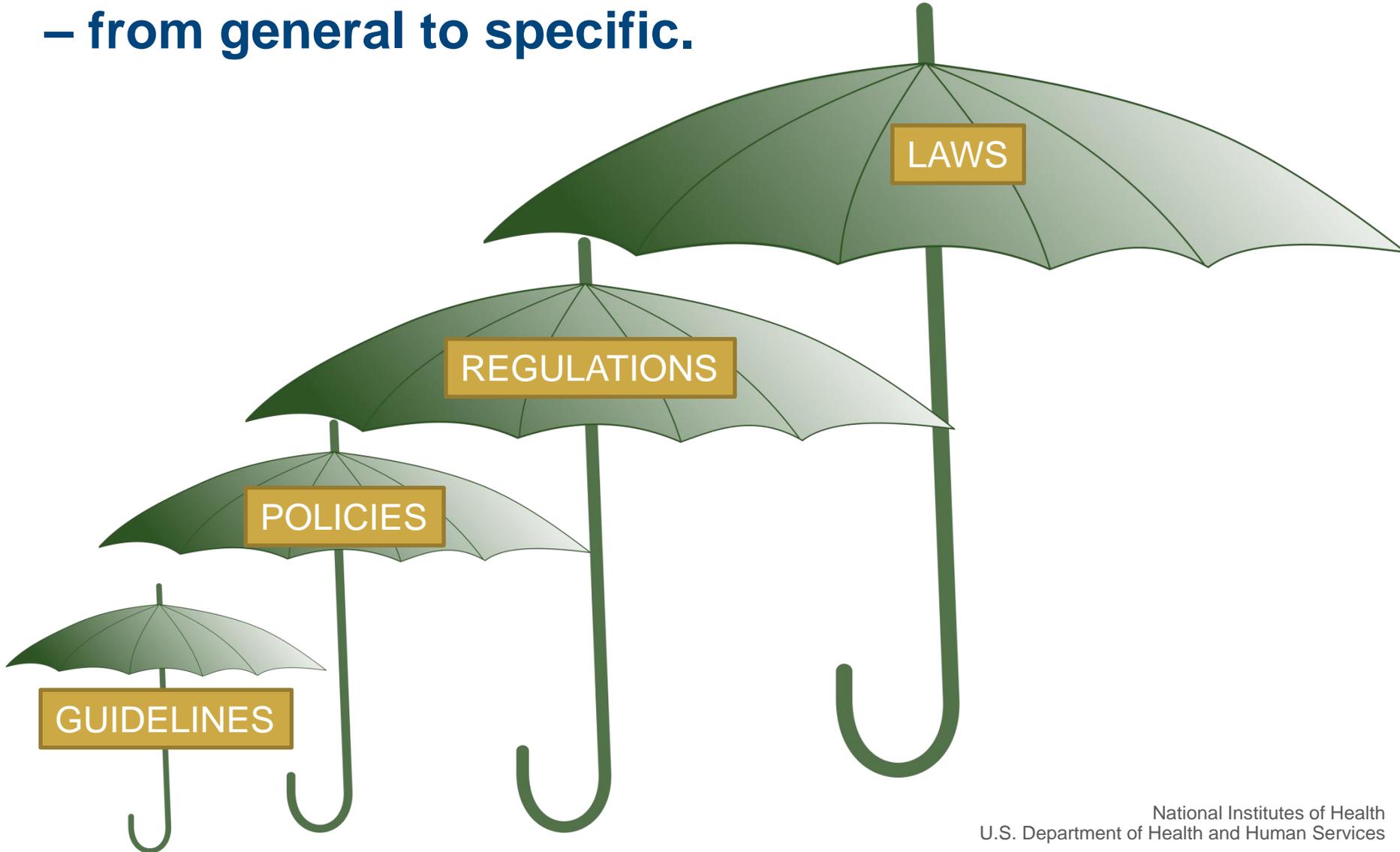
- Help organizations “think like a Grants Management Specialist” when facing policy/procedure questions on PEPH research grants.



Purpose of the Webinar:

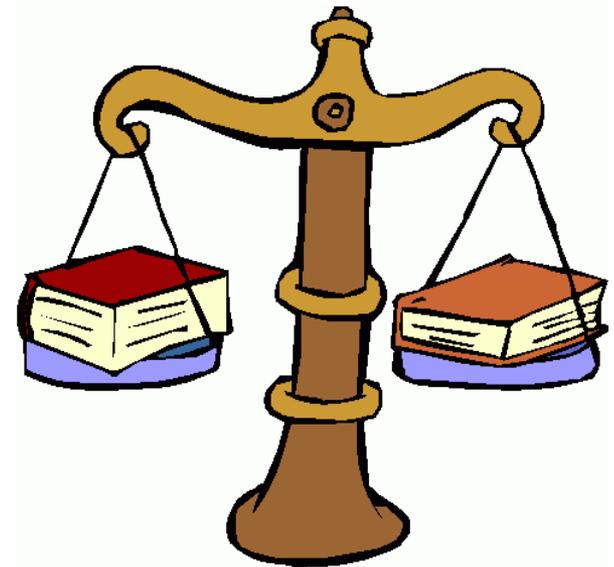
- Help organizations “think like a Grants Management Specialist” when facing policy/procedure questions on PEPH research grants.
- Provide a framework for organizations to learn more about the policies, rules, and regulations.
- Walk through some common cases, to see how policies apply:
 - Establishing a consortium agreement
 - Establishing an indirect (F&A) cost rate
 - Engaging in human subjects research

Grants Management rules are set up in a hierarchy – from general to specific.



The Levels of Grants Rules

- Laws – Passed by Congress
 - Freedom of Information Act – [5 USC 552](#)
 - Annual Appropriations, e.g. [“HR.83/Public Law 113-235”](#)
 - Agency Authorizations, e.g. [“HR 6164/Public Law 109-482”](#)
- Regulations
- Policies
- Guidelines



The Levels of Grants Rules

- Laws
- Regulations – How the Executive Branch Interprets the Law
 - 2 CFR 200 “Uniform Grant Guidance”
 - 45 CFR 75 “HHS Implementation of Uniform Grant Guidance”
 - 45 CFR 46 “The Common Rule” for Human Subjects
- Policies
- Program Guidelines



The Levels of Grants Rules

- Laws
- Regulations
- Policies – How agencies interpret the regulations
 - [NIH Grants Policy Statement](#)
 - [HHS Grants Administration Manual](#)
 - [Form Instructions \(e.g. SF 424 R&R\)](#)
- Program Guidelines



The Levels of Grants Rules

- Laws
- Regulations
- Policies
- Program Guidelines – how a specific program interprets the policies
 - Program Announcements
 - Funding Opportunity Announcements
 - Terms of Award
 - Program Websites

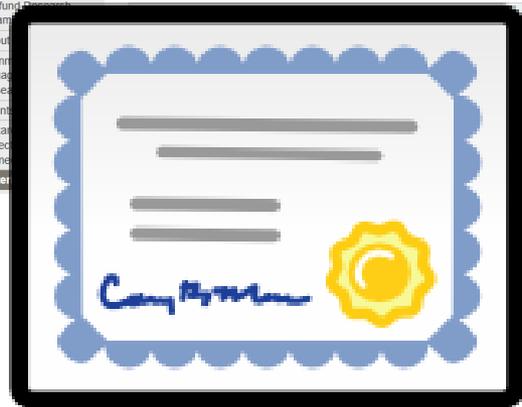
Weekly NIH Funding Opportunities and Notices
 NIH Guide for Grants and Contracts
 September 25, 2015
 Table of Contents (TOC)

All NIH Funding Opportunities and Notices

Notices

- [Webinars for Applicants and Grant Administrators: What You Need to Know About NIH Application Submission and Review \(NOT-OD-15-154\)](#)
National Institutes of Health
- [Notice of Participation of the Office of Research Infrastructure Programs in PA-14-157 Early Stage Development of Technologies in Biomedical Computing, Informatics, and Big Data Science \(R41/R42\)](#)
(NOT-OD-15-157)
Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs
- [NIH Research Involving Introduction of Human Pluripotent Cells into Non-Human Vertebrate Animal Pre-Gastrulation Embryos](#)
(NOT-OD-15-158)

The screenshot shows the NIH website interface. At the top is the NIH logo and tagline. Below it are navigation tabs for Health & Education, Research, Funding Opportunities, Careers & Training, News, and About NIEHS. A sidebar menu is open, listing various research programs and funding opportunities. The main content area displays 'Materials for Grantees' and 'Superfund Research Program' with a brief description.



Where do you find the policy answer?

- Program Guidelines often are the most relevant to the specific situation, but leave out operational details that pertain to general administrative questions.
- Program Guidelines reference the Policies, Regulations, and Laws that apply.
- To answer a specific question, start specific and go general:
 - Notice of Award → Federal Law
- If you're designing a general SOP, start general and go specific
 - Federal Regulations → Agency/ Program Guidelines



Case 1: Establishing a consortium agreement



Program Guidelines can answer questions about participation in a program:

- Is your organization eligible to receive support for this program?
- Does the program require community participation?
 - Is there a budget set-aside requirement for community engagement?
 - Does a community partner need to serve as key personnel?

NIH Policies can provide a framework for consortia participation:

- Per NIH Grants Policy Statement, Section 15
 - Public Policy requirements must “flow-through” the recipient to the consortia organization.
 - That means that if a consortium is a non-profit org, the non-profit rules apply to the consortium, even if the prime recipient is a university or hospital.
 - Consortia must enter into a formal written agreement.

Recommended Components of the Written Agreement

- Who will be doing the work, and in what capacity?
- How will the research effort be conducted and monitored?
- How will the consortium be reimbursed? How will rebudgeting be accommodated?
- How will the recipient measure the consortium partner's compliance with policies (e.g. Financial Conflict of Interest)?
- Who will own the data and publications rights when the work is over?

See [NIH Grants Policy Statement Section 15.2.1](#) for full details.

What NIH cannot do:

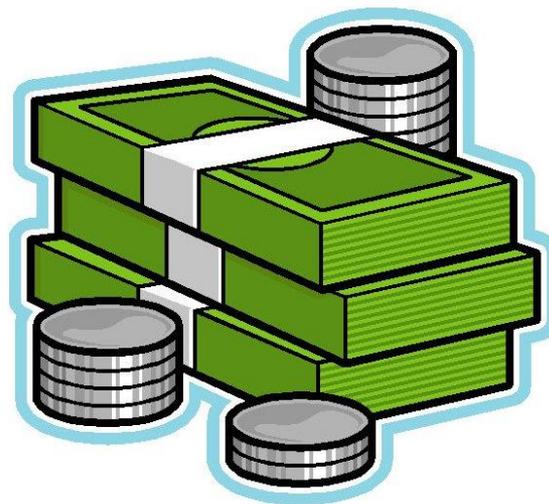
- NIH requires a written agreement, but cannot dictate the terms of the written agreement.
- NIH does not have a direct fiscal relationship to the consortium, and in most situations cannot directly intercede in disputes or officially correspond with the consortium organization.



What about Laws and Regulations?

- Laws and Regulations indicate that consortia are allowable on grants and indicate what public policy requirements apply.
- See 45 CFR 75 subpart D, for “Subrecipient Monitoring and Management” for what information recipients need to receive from consortia.

Case 2: Establishing an Indirect (F&A) Cost Rate



The Good News:
You have **OPTIONS!**

Where to find out about the options

- Program Guidelines indicate whether indirect costs are allowable on a specific program.
 - Note: Conference grants (R13s) do not allow indirect costs at all and some training programs include reduced indirect costs at a fixed rate.
- Agency Policies can provide more information
 - NIH [Grants Policy Statement Section 7.4](#) outlines allowable options for NIH awards.
- Regulations – Uniform Grants Guidance – outline options on how to allocate costs and calculate rates.

Option 1: Federally Negotiated Rate

- A formal rate can be negotiated with HHS if you are the direct recipient of a federal grant.
- The rules used for setting this rate are described in 2 CFR 200 / 45 CFR 75.
 - There is a “Simplified Allocation Method” and a “Multiple Allocation Base Method” to accommodate organizations of different sizes and purposes.
- If you are a consortium, the recipient organization may act as the “cognizant” agency and negotiate a rate with you following the rules in 2 CFR 200 (45 CFR 75 for NIH grants).

See [9/11/15 Rock Talk](#) for a demystifying of indirect cost rates



Option 2: Accept a 10% *de minimus* Rate

- When 2 CFR 200 “Uniform Grant Guidance” replaced OMB Circular A-122 in 2014, the option to take a 10% MTDC* *de minimus* F&A rate was made available.
- The 10% rate does not require prior negotiation, but does require proper post-award documentation to make sure that funds are only used for allowable “Facility & Administrative” costs.
- This option is only available for organizations that have NEVER established a federally negotiated rate.

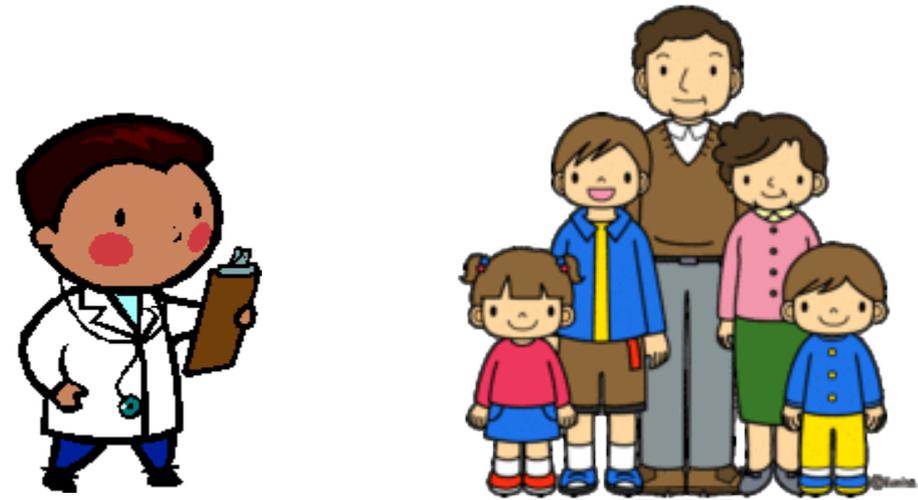
*MTDC = modified total direct costs, which means all direct costs except some special items like tuition, equipment, rent, and the portion of subawards exceeding \$25,000.

Option 3: Direct Charge F&A Costs

- The NIH Grants Policy Statement and Uniform Grants Guidance Cost Considerations identify several items as “generally treated as F&A costs”(e.g. rent, library services, IRB services).
- If your organization only has a single award/project and can document that costs normally considered “F&A” pertain only to that specific project, many of those costs can be listed as direct costs.
- Your budget justification should point out that you are directly charging these costs rather than applying an indirect rate.



Case 3: Engaging in Human Subjects Research



How does your organization know if it is engaged in human subjects research?

- NIH Program Guidelines and Policies all point to the Regulation 45 CFR 46, better known as “The Common Rule” for human subjects guidance.
- The Common Rule indicates each project should ask:
 1. Is this project research? Research: A systemic investigation designed to develop or contribute to generalizable knowledge.
 2. Does this research involve obtaining information about living individuals?
 3. Will the research involve direct interaction/intervention with the individuals? If not, will private individually identifiable information be available to the researchers?

Example 1: Conducting Community Focus Groups

1. Is this research?
 - Probably – if the focus group is intentionally designed and its purpose is to gain knowledge that could be generalizable.
2. Are you obtaining information from living individuals?
 - Yes
3. Are you directly interacting with the individuals or collecting privately identifiable information?
 - Probably - it depends on the design.

ANSWER: YES, this is likely Human Subject
Engagement



Example 2: Putting out a newsletter sign-up sheet at a Town Hall Meeting

1. Is this research?

- If the sole purpose of the sign-up list is to help disseminate information (not collect information), then NO this is not research. If you can say “NO” to a question, stop.



2. Are you obtaining information from living individuals?

- Yes

3. Are you directly interacting with the individuals or collecting privately identifiable information?

- Yes

ANSWER: This is only human subjects research, if this meets the definition of research.

Example 3: You design an informational website, which includes a visitor survey.

1. Is this research?

- Maybe – e.g. if you are comparing multiple design options for message effectiveness.

2. Are you obtaining information from living individuals?

- Yes

3. Are you directly interacting with individuals or collecting identifiable information?

- Possibly not – is the survey anonymous?

Answer: IT DEPENDS – it may or may not be HS research.



Requirements for Engagement of Human Subjects Research

- Institutional Review Board (IRB) Review*
- Federal-wide Assurance*
- Verification of Education on Protection of Human Subjects
 - Applies to anyone who helped design the project, or will directly be interacting with research subjects, or have access to identifiable information.
- *Exempt projects do not need to have FWA or IRB approvals, but do need Human Subjects Protection Education.
- Clinical Trials also need a Data and Safety Monitoring Plan.

Exemptions for Human Subjects Research

- Exemption 1 – Conducting an educational intervention in normal educational setting.
- Exemption 2 – Using psychological tests, interviews, surveys, or observations that do not identify individuals or pose risk.
- *Exemption 3 – Exemption 2, but individuals are identified as publicly elected officials.*
- Exemption 4 – Using existing publicly available data (e.g. published census data).
- *Exemption 5 – Demonstration projects of federal programs.*
- *Exemption 6 – Taste / Food quality tests.*

Resources about Human Subjects Research

- HHS Checklist & Decision Trees for Human Subjects Engagement:
<http://www.hhs.gov/ohrp/policy/checklists/index.html>
- NIH Office of Extramural Programs FAQs on Human Subjects: <http://grants.nih.gov/grants/policy/hs/faqs.htm>.
- Human Subjects issues can be complex. When in doubt, ask your NIH program officer.



Final thoughts....

