The NIH Review Process

The Principal Investigator

- Principal Investigators:
  - Responsible for science & day-to-day management of project.
  - Responsible for project's technical, financial, and administrative compliance.
  - Usually a single individual, although there may be multiple PI's for team science projects.
- PI works with institutional officials to:
  - Create & maintain award documentation, including technical & administrative reports
  - Prepare budget and justification
  - Ensure appropriate acknowledgement of sponsor support in publications, announcements, etc.
  - Comply with organizational and sponsor requirements.

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Grantee Organization

- Recipient of the funds
- Institution not PI
- Responsible and accountable for the use of funds and for the project's technical performance.
- Must possess institutional infrastructure to assure compliance with all applicable policies, Federal statutes and regulations.

Authorized Institutional Official

- Designated representative of grantee organization in all matters related to the award.
- Signature of this official is required for all official correspondence to sponsor.

AOR, SO, AIO…LEAR

- This Official's signature on a grant application or contract proposal
- Certifies applicant institution will comply with all applicable assurances & certifications referenced in the application.
- Assures applicant institution will be accountable for the appropriate use of funds and performance of grant-supported project.
- Attests that all information contained in the application is true, complete & in conformance with sponsor and institutional requirements.

Financial Terms You Should Know

Direct Cost	• Costs that can be identified specifically with a particular sponsored project relatively easily with a high degree of accuracy
F&A (Indirect Cost)	• Costs that are incurred for common or joint objectives and therefore cannot be identified readily and specifically with a particular project

Other US Grants Terminology

- Key Personnel: Investigators with measurable effort considered to be of primary importance to the successful conduct of the project.
- Other Significant Contributors: Investigators committed to the project with no measurable effort.
- Other Support: All financial resources providing direct support to an Investigator's research endeavors. Includes research grants, contracts, cooperative agreements and institutional awards. Excludes prizes and gifts.
- Notice of Grant Award: NoGA or NGA

Peer Review

Primary basis for most funding decisions

- Peer review (often federal)
- In house (often private foundation)

Peer review panels may be

- Either ad hoc or pre-defined
- Mail review or panel review
- Role of program official is a variable

Some contract procurements may be based on a combination of merit and proposed cost

Typical Peer Review

Peer Review Criteria

- Conformity to goals of sponsor
- Quality of proposal
- Soundness of proposal
  - budget
  - program
  - space, resources, personnel

Peer Review Outcomes

- Probability of accomplishment
- Evaluations are anonymous, and given in summary form to applicant on request
- Reviews usually assign scores, rankings, or categories
- Funding decisions are based on available funds
- Amount of award may be unilateral, or may be negotiated
- See program guides or solicitation for details about review

Rejections

If a proposal is rejected, the PI should obtain the reviews from the sponsor and resubmit

- Sponsored projects administrators should:
  - convey an offer to PI that they are willing to help the PI resubmit and/or find other potential sponsors
  - identify faculty colleagues who may serve as mentors
  - assure faculty that rejection is “normal” and resubmission is best strategy for long-term success

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The Experience of a NIH reviewer

COMPLIANCE ISSUES

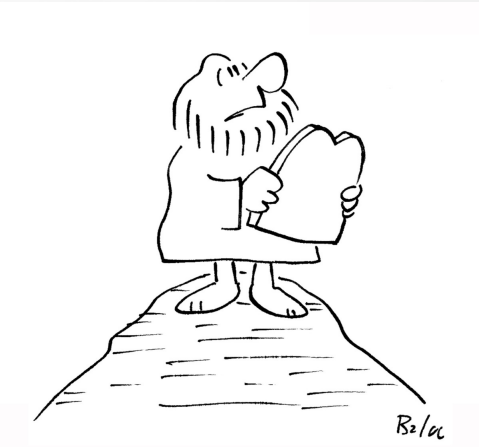
ENSURING COMPLIANCE

Important compliance issues for non-US participants

Most everything we do is compliance

But, there are some major areas:

- Responsible conduct of research
- Research misconduct
- Conflict of Interest
- Protection of human subjects
- Use of animals in research
- rDNA
- Export controls



"How long do we have to get in compliance?"

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WHY IS COMPLIANCE IMPORTANT?

The conduct of research is a privilege granted by society

The granting of the privilege is based on the public's trust that research will be conducted responsibly

Erosion of that trust can result in the public's withdrawal of the privilege

Public trust is maintained through ethical action, and institutional and individual accountability

What is the Uniform Guidance (UG!)?

- OMB's consolidation of circulars for costing, administration and audit of Federal awards
  - 2 CFR 200 replaces 8 circulars and applies to universities, state and local governments, nonprofits, native tribes
  - Issued on December 26, 2013
  - Effective largely on December 26, 2014
- Biggest change in Federal regulations in 50 years
- Some good news, some new administrative burdens
- Each Federal agency will implement a slightly different version of the UG
- UG is still being interpreted and clarified

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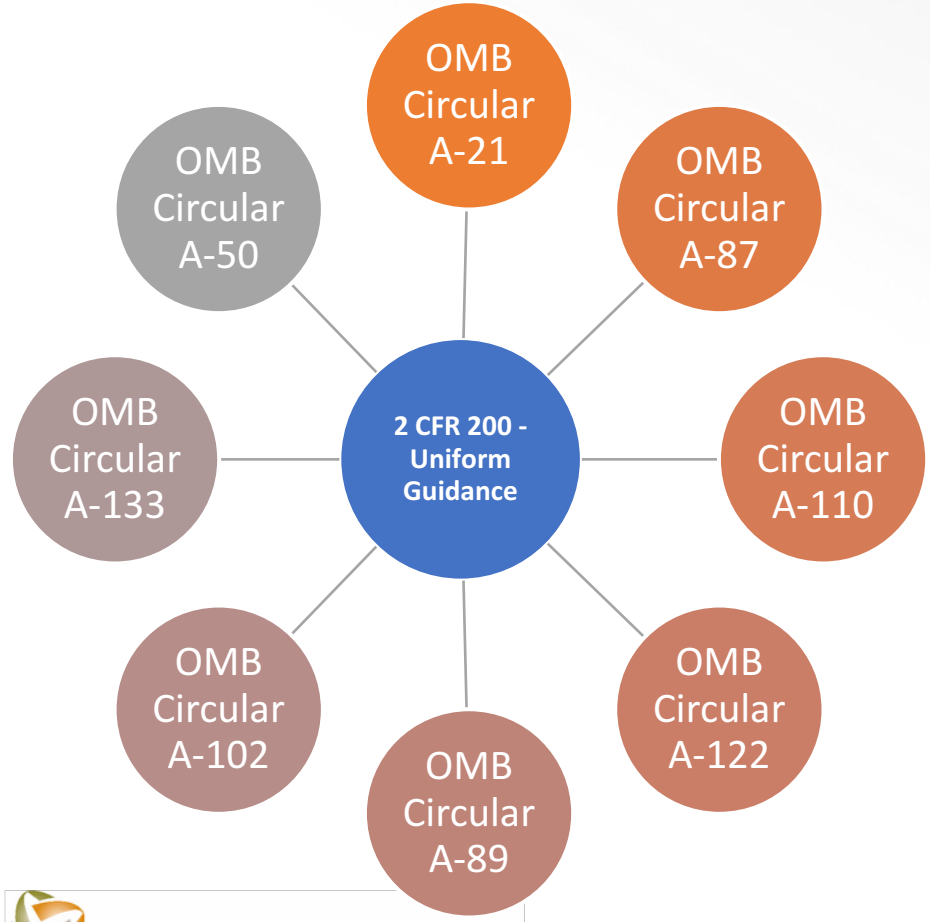
Uniform Guidance (UG):

Combined Version of 8 Circulars



Sections of the Guidance

Subpart A:
- Acronyms and Definitions

Subpart B:
- General Provisions

Subpart C:
- Pre-Award Requirements

Subpart D:
- Post Award Requirements

Subpart E
- Cost Principles

Subpart F
- Audit Requirements

Appendices
- Funding opps, F&A, etc.

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Federal Goals for Uniform Guidance

- Streamline guidance for Federal awards to ease administrative burden
- Strengthen oversight over Federal funds to reduce risks of fraud, waste, and abuse
- Improve performance over compliance for accountability
- Encouraging efficient use of information technology and shared services

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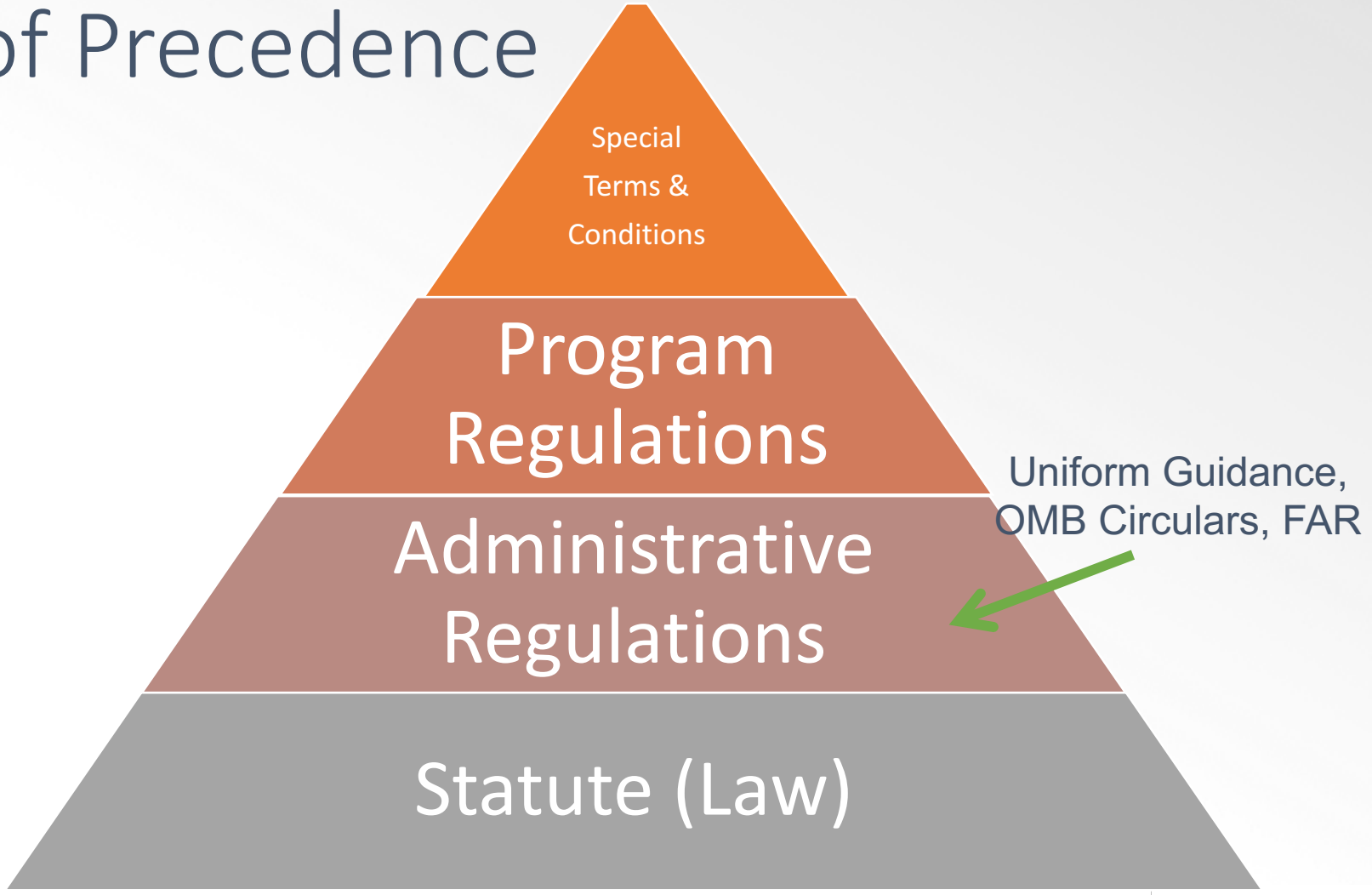
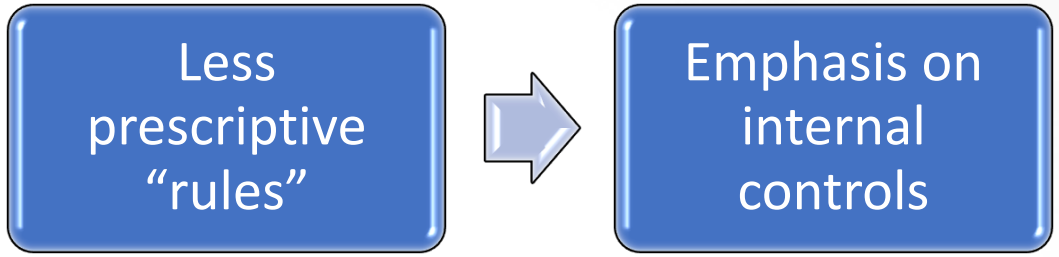
Order of Precedence



Internal Controls

- More Emphasis on Internal Controls
  - Our internal controls are already being evaluated for adequacy and effectiveness – Single Audit (formerly A-133 audits)
  - Focus on Internal Controls when revising policies and procedures



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UG Top 10 List for International Partners

1. Notice of funding opportunities (200.203(b))
2. Subrecipient monitoring and management (200.330-200.331)
3. Indirect costs (200.414)
4. Fixed amount subawards (200.332)
5. Closeout (200.331(a)(6) and 200.343)
6. Exchange rates (200.440)
7. Taxes (200.470(c))
8. Recruiting costs (visas) (200.463(d))
9. Allowable Costs (Subpart E – Cost Principles)
10. Prior approvals (200.308 and 200.407)

https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title02/2cfr200_main_02.tpl

Other Uniform Guidance Resources

- Columbia University: http://spa.columbia.edu/uniform-guidance
- Emory University: http://www.ogca.emory.edu/ugep/index.html
- Harvard :http://osp.fad.harvard.edu/content/new-omb-uniform-guidance
- MIT: http://osp.mit.edu/grant-and-contract-administration/sponsored-programs-basics/ombs-uniform-guidance
- Michigan State University: https://www.cga.msu.edu/PL/Portal/DocumentViewer.aspx?cga=aQBkAD0AMgA5ADkA
- University of Maryland College Park: http://www.ora.umd.edu/resources/federal/uniform-guidance
- University of Michigan: http://orsp.umich.edu/policies/federal/omb-guidance/
- University of Minnesota: http://www.ospa.umn.edu/documents/UG.html
- University of Pennsylvania: http://www.upenn.edu/researchservices/OMB%20Announcement.html
- University of Wisconsin: https://www.rsp.wisc.edu/UG/

INSTITUTIONAL RESPONSIBILITIES under the *NIH Guidelines*

Establish and implement policies for the safe conduct of recombinant DNA research
Establish an Institutional Biosafety Committee
Assist and ensure compliance with the NIH Guidelines by investigators
Ensure appropriate training for IBC members and staff, PIs, laboratory staff
Determine necessity for health surveillance of personnel
Report any significant problems or violations to Office of Biotechnology Activities within 30 days

Responsible Conduct of Research (RCR)

NSF, USDA NIFA, and NIH have some form of RCR training requirements dependent on type of award/participant in the following areas:

- Data acquisition, management, sharing, and ownership
- Mentor/trainee responsibilities
- Publication practices and responsible authorship
- Peer review
- Collaborative science
- Human subjects
- Research involving animals
- Research misconduct
- Conflict of interest and commitment

Institution determines content, length, format, and who covered

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RESEARCH MISCONDUCT

"fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results."

does not include honest error or honest differences in interpretations or judgments of data.

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FEDERAL SCIENTIFIC MISCONDUCT DEFINITIONS

Fabrication is making up data or results

Falsification is manipulating, changing, or omitting data or results

Plagiarism is taking another person's ideas, processes, or words without giving appropriate credit

65 FR 22286 (12/6/2000)

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RESEARCH MISCONDUCT

Institutions must develop policies and procedures for allegations of misconduct:

- Definitions
- Written policy – assurance of confidentiality
- Description of inquiry and investigational phases
- Process for protection of whistleblowers
- Protection of research subjects
- Reporting to agency (process/timing)
- Retention of records
- Certification requirements

DHHS requires assurance via Annual Report on Possible Misconduct under ORI

U.S. EXPORT CONTROL AUTHORITIES

Treasury Department	Commerce Department	State Department
Office of Foreign Assets Control (OFAC)	Bureau of Industry and Security (BIS)	Directorate of Defense Trade Controls (DDTC)
Foreign Assets Control Regulations	Export Administration Regulations (EAR)	International Traffic in Arms Regulations (ITAR)
Sanction Programs	Commerce Control List (CCL)	United States Munitions List (USML)
Prohibits transactions with countries, entities and persons subject to boycotts, trade sanctions and embargoes	Exports and re-exports of dual-use commodities, software, equipment and technology	Transfers of defense articles and provision of defense services; inherently military technologies

LICENSING AND EXCLUSIONS

An export license may be required before a controlled item or technical data about a controlled item may be exported.

If a license is required and denied, export or deemed export is prohibited.

Most university research and teaching qualifies for regulatory exclusions or license exemptions.

IMPLICATION OF EXPORT LAWS

No effect on vast majority of university research

But potential impact on:

- Ability of foreign students to participate in research involving a controlled technology (mostly under ITAR)
- Ability to provide services (including training in the use of controlled equipment) to foreign nationals (ITAR, EAR, OFAC)
- Ability to send controlled equipment to foreign countries (ITAR, EAR, and OFAC)