



International regulations, national implications

Domestic countries, roll-up your sleeves!

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First Draft

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4 days before the session

International regulations, national implications

- Outline
 - The background
 - International regulations and national implications
 - Examples
 - Discussion

Background

- What are international regulations?

{developing country's perspective; mostly universally defined; human subject/trial insurance/data sharing etc.}

- Why are those important to be adhered to?

{Responsible conduct; legal binding;; audit/compliance issues; donor requirement (outside of the contract); enhanced credibility; success stories; more grants}

- What do developing countries have to do with the international regulations?

{Flow Down clauses; growing attitude for responsible conduct (NBC); flowing the clause further down to sub-awardees}

- Are there any national regulations that overlap with the international ones?

{Yes!; human subject/animal subject; insurances;

International regulations, national implications

- Most commonly used international regulations:
 - Conflict of Interest and Conflict of Commitment {§ 200.112}
 - Effort Reporting {§ 200.430}
 - Certs and Reps {§ 200.208}
 - Allocation & Allowability {§200.4 & § 200.403}
 - Cost sharing / Matching {§ 200.209}
 - Single Audit / program-specific audit {§ 200.507}
 - HIPAA (1996)
 - Intellectual Property and allowable costs {§ 200.448}
 - Indemnification {§ 200.447}
 - Retention requirement for records {§ 200.333}
 - Order of Precedence
 - Suspension and Debarment {§ 200.213}

Examples

- Conflict of Interest {§ 200.112}

Challenges & Implications	Strategies that work
<ul style="list-style-type: none">a. Lack of awareness and non-adherenceb. Disallowance of costs if a conflict is observed laterc. Debarment /Suspension	<p>Educate ourselves first.</p> <p>Development and implementation of a written down Col policy which includes a CoC aspect as well.</p> <p>Communication of the said policies to concerned faculty/staff and entities.</p>

Examples

- Effort Reporting {§ 200.430}

Challenges & Implications	Strategies that work
<ul style="list-style-type: none">a. Lack of awareness and non-adherenceb. Concept of IBSc. Lack of availability of multi-grant charging payroll system	<p>Educate ourselves first.</p> <p>Implementation of multi-grant charging payroll system (where required).</p>

Examples

- Certs & Reps {§ 200.208}

Challenges & Implications	Strategies that work
<ul style="list-style-type: none">a. Signing without reading and understanding.b. Anti-lobbying, Anti-terrorism etc.c. Who shall sign?	<p>Engage legal counsel to make local team understand the Certs and Reps and then if found conforming, sign.</p> <p>External legal consulting services are also available.</p>

Examples

- Allocation and Allowability {§ 200.4 & 200.403}

Challenges & Implications	Strategies that work
<ul style="list-style-type: none">a. How to allocate versus how to charge?b. What do we mean by “reasonable proportion?”c. Who shall sign?d. Consistency, adequacy, GAAP.	<p>Example: Rent of a shared office. What %age of resources a specific project is taking. Use that %age to charge.</p> <p>Development of basis for cost allocation at the start of the project not at the conclusion.</p>

Examples

- Cost Sharing and Matching {§ 200.209}

Challenges & Implications	Strategies that work
a. How to verify the cost sharing from records?	Externally audited accounts by an accredited auditing firm.
b. In-kind cost sharing? Is it acceptable?	In-kind is permissible.
c. Cost sharing mentioned for one Fed award. Can it be used as a cost share for another award?	
d. Cost supported by Fed award. Can it be used to show cost sharing for another?	

Examples

- Single Audit / Program-specific Audit {§ 200.507}

Challenges & Implications	Strategies that work
a. GAGAS (Generally Acceptable Government Auditing Standards)	First determine applicability of audit on your award
b. Compliance Supplement (audit guide)	Check for audit guide if available
c. What happens when audit guide is not available?	Follow the rules diligently.
d. Threshold level for single audit.	
e. Who bears the cost of audit?	

Examples

- HIPAA

Challenges & Implications	Strategies that work
a. No central private insurance system for labor force	Institutional staff and family insurance (which is available in most of the cases) is explained and negotiated with the cognizant federal agency.
b. No government system for uninterrupted insurance for labor force	De-identified data is maintained in most of the institutions.

Examples

- Intellectual Property and allowable costs {§ 200.448}

Challenges & Implications	Strategies that work
<p>a. Can we charge the cost of patent filing and preparation?</p> <p>b. To what extent patents are protective in one's country if the research is funded by an international agency or Government?</p>	<p>Only as required by the respective federal award.</p> <p>Even royalties are allowed (with some exceptions).</p>

Examples

- Indemnification {§ 200.447}

Challenges & Implications	Strategies that work
<p>a. Can the cost of insurance of project staff and equipment be done?</p> <p>b. Most organizations do not have a staff / property insurance system or a very modest one.</p>	<p>Yes it can be (with some minor exceptions)</p> <p>Ascertain the extent of risk involved in the delivery of the project deliverable, the budget accordingly.</p> <p>Actual loss incurred that may have been prevented due to permissible insurance are NOT allowed.</p> <p>Indemnification is also allowed (including Medical Malpractice).</p>

Examples

- Retention requirement for records {§ 200.333}

Challenges & Implications	Strategies that work
a. A lot of the work is manual and hence records are kept in hard copy hence the cost of physically keeping three year records post submission of final financial report* is significant.	<p>Develop electronic model of records from the start of the Project.</p> <p>For hard copies, use data scanning to make those electronic.</p> <p>(the regulation does not mention whether it means hard copy retention or soft copy retention of records)!</p>

Examples

- Order of precedence

Challenges & Implications	Strategies that work
<ul style="list-style-type: none">a. Confusion!b. What to follow when?c. Deriving advantage out of this confusion for our convenience and interest.	Award document needs to clearly mention that it is the FIRST document that should be referred to when making decisions on Administration, Costing, Accounting, and Audits.

Examples

- Suspension and Debarment {§ 200.213}

Challenges & Implications	Strategies that work
<ul style="list-style-type: none">a. Lack of knowledgeb. How, when and where to look for debarred or suspended entities ?	Check for 2 CFR Part 180. It contains all the details.

Discussion and Questions

Thank you for your attention!
for any questions or comments
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