Navigating Federally Sponsored Projects Abroad

Common Compliance Challenges and Solutions

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Agenda

- Background and Context
- Establishing and Setting Up Foreign Research Operations
  - Threshold considerations and diligence (Africa example)
  - Site establishment
- Challenging Financial and Administrative Considerations Under Federal Awards
- Clinical Research Complexities
  - Common Rule compliance challenges
  - Other U.S. laws and non-U.S. laws

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Background and Context

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Background & Context

- Growth in sponsored projects complexity
  - E.g., multi-site projects
- Growth in volume of sponsored projects
  - E.g., U.S. and non-U.S. sponsors, industry sponsors
- Growth in research constituents
  - E.g., multiple departments, disciplines
- Sponsors demanding lower cost, greater efficiency
- Numerous and diverse areas of potential noncompliance
- Risks of noncompliance are high
- Federal and state law empowers whistleblowers
- INTERNATIONAL ENGAGEMENT IS A PRIORITY

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Government's Recent Focus on Audit/Enforcement in Federal Grants

Date	Sponsor	Issues	Settlement/Enforcement Actions
March 2019	NIH, EPA	• False statements in grant application/reports	Grantee agreed to pay $112.5M
May 2018	HHS	• Administrative costs	$8.6M in questioned costs
February 2018	NIH	• Effort reporting	Grantee agreed to pay $13M
March 2017	HHS	• Subawardee monitoring	$299K in questioned costs
December 2016	HHS	• Administrative/clerical costs • Supporting documentation • Effort reporting • Grant oversight	$1.3M in questioned costs
November 2015	HHS	• Effort reporting • Administrative costs	Grantee agreed to pay $19.8M
March 2015	NSF	• Excessive compensation • Relocation costs • Travel costs	$1.7M in questioned costs
October 2014	CDC	• Effort reporting	Grantee agreed to pay $9M

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Background & Context

- **Spectrum of International Projects**
  - Education/Training ⟷ Technical Assistance ⟷ Clinical Trials
  - Lower cost & risk ⟷ Higher cost & risk
- **Why is public health research going global?**
  - Perceived lower cost.
  - Ideal study populations.
  - Tremendous need (e.g., Africa).
  - Foreign governments make attractive investments.
  - Sponsors encourage foreign collaboration.
  - Prestige.

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Background & Context

Examples of Sponsored Projects

- HIV/AIDS care, treatment, drug delivery (e.g., PEPFAR).
- Capacity building, health systems, and consulting.
- Collaborations with foreign universities, hospitals, nonprofits, companies, and governments.
- Clinical trials.

Sources of funding

- U.S. government (e.g., NIH, CDC, HRSA, USAID, State Dept.).
- European Union (Horizon 2020, Framework Programme).
- Industry (e.g., pharmaceuticals).
- United Nations, World Bank, IMF.
- Gates Foundation and other charities.

Background & Context

- **Regulatory spotlight on "foreign components" of sponsored projects:**
  - "The Agency audited just the foreign component of the project."
  - "Contract templates were not suited for use overseas."
  - "Records did not substantiate salary costs at the foreign location."
  - "The foreign subrecipient did not understand its obligations."
  - "No review of the foreign subrecipient's cost accounting infrastructure."
  - "Currency exchange gains/losses went unrecorded."
  - "Foreign taxes were deemed ineligible costs."
  - "Questionable benefits and allowances were paid to foreign staff."
  - "Our foreign location did not comply with foreign law."

Foreign site establishment

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Diligence at an early stage

Operational assessment

- What kinds of approvals/licenses/registrations will we need?
  - Structuring "lite" vs. registration/entity establishment
- Third party/outsource resources available?
  - Challenge your assumptions about foreign "partners"
- Entity/employment set-up complexities and timing
- Risk assessment (liability, oversight, security, access, evacuation)
- Gauge reliability of your lead personnel overseas
- How do we wind up?

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Diligence at an early stage

Ethical, social, and cultural norms

- How meaningful is a contract?
- Sensitivity to certain types of scientific and other programs
- Conflicts of interest
- Corruption indicators

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Example: Africa site threshold considerations

- Each country is unique – legally, culturally, politically
- Uneven enforcement of local law
- Inflexible and bureaucratic regulators, but growing sophistication
- Frustrating delays and inefficiencies
- Unreliable “exceptions” and no “benefit of the doubt” for nonprofit, research, humanitarian, charitable activity
- Stringent local labor and tax law
- Local site conditions are irregular (roads, safety, security)
- Corruption and bribery; conflicts of interest
- Lingering distrust and suspicion of Western organizations

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Registration triggers: "Doing business" abroad

- Opening a bank account
- Employing even one person
- Posting a researcher to the foreign location
- Administering clinical research or patient care
- Leasing property
- Enrolling subjects in a trial
- Buying a vehicle or major equipment
- Removing biospecimens from the host country

These activities often trigger registrations and other obligations in host countries.

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Examples of legal/operating structures abroad

- Identifying a local partner or "best friend" to operate through
- Direct agreement with host country (e.g., MOU)
- Engaging a professional employer organization (PEO)
- Registering a "branch office" of the institution
- Formation of a:
  - New nongovernmental organization (NGO)
  - New "company limited by guarantee" or nonprofit company
  - "For profit" subsidiary
  - "Special purpose entity" (SPE)
  - Separately controlled legal entity - can raise complex issues

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Challenging Financial and Administrative Considerations Under Federal Awards

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Expatriate benefits under federal projects

Context

- U.S. personnel posted abroad (expats) often expect a competitive package of benefits and personal allowances.
- Expats may expect/receive:
  - Housing allowance
  - Airfare and automobile allowance
  - Cost-of-living adjustments
  - Travel and relocation benefits
  - Education allowance
  - Mobile phone and communications allowance
  - Utility supplements
  - International tax advice and tax equalization
- Alignment with local law, norms, and customs
- Challenging to establish and consistently apply an institutional expatriate benefits policy

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Expatriate benefits under federal projects

OMB Uniform Guidance

- Cost of goods or services for personal use of employees are unallowable.
- Cost of housing (depreciation, maintenance, utilities, furnishings, rent, etc.), housing allowances and personal living expenses are only allowable as direct costs regardless of whether reported as taxable income, and must be approved in advance by the sponsor. (UG § 200.445).

- Some issues…
  - Implication is that certain expat benefits are unallowable unless there is prior written approval
  - Is prior approval more than approval of a budget that includes these costs?
  - Sponsor may request the institution's policy on expatriate benefits.
  - Goods, services, and housing provided as part of a compensation package will not make an otherwise unallowable cost allowable. (UG § 200.430(d)(1)).

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Foreign taxes under federal projects

OMB Uniform Guidance

- Foreign Value Added Tax (VAT) charged for the purchase of goods and services that a grantee is legally required to pay in country is an allowable expense. (UG § 200.470).
- But see NIH Grants Policy Statement: "For many countries an exemption of this tax for research exists. Consequently, requesting this cost should be unallowable for research grants involving such countries as a performance site."

- Some issues…
  - When is an institution "legally required to pay"?
  - Effect of bilateral treaties between the US and host country (some offer tax exemption)
  - Exemptions are difficult to apply for and burdensome to operationalize
  - Unallowable VAT has become a common audit finding

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Foreign office/site set-up costs

- Who pays?
  - Project, department, school, CFO's budget?
- Allocable to federally sponsored projects?
  - E.g., leases; payroll providers; office supply and furniture; vehicles; legal fees
  - Administrative and clerical salary – e.g., office receptionist, IT
    - Under UG § 200.413, direct charging of admin/clerical salary to federal projects appropriate only if:
      1. Administrative and clerical services are integral to the project;
      2. Individuals involved can be specifically identified to the project;
      3. The costs are explicitly budgeted and have prior written approval from sponsor; and
      4. The costs are not also recovered as indirect costs.

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Monitoring foreign subrecipients

Context

- Foreign subrecipient monitoring is among the most challenging of all prime awardee obligations.
- Sponsors hold prime awardee accountable for the foreign subrecipient's costs and compliance.
- Uniform Guidance requires prime awardees to evaluate subrecipient's risk of noncompliance to determine level of monitoring.
- For high risk foreign subrecipients, some prime awardees have used "fixed price subawards."
  - Uniform Guidance precludes fixed price subawards without prior written approval; the amount must be below the Simplified Acquisition Threshold, and the subaward must meet requirements in UG § 200.201. (UG § 200.332).

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Monitoring foreign subrecipients

Some issues…

- Audit issues have been tied to (1) incomplete diligence on foreign clinical sites; (2) poorly drafted foreign subawards; and (3) absence of monitoring.
- Thoroughly vet foreign subrecipients prior to subaward.
  - Inquiry into subrecipient's financial management system, timekeeping policies, prior audits, key personnel, training policies, personnel policies, registration status, etc.
- Counsel should be involved in foreign subaward drafting.
  - Old subaward templates must be updated to reflect Uniform Guidance requirements.
- Implement/apply subrecipient monitoring policies and procedures.

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Other challenges with sponsored projects abroad

- Working through Professional Employment Organizations (PEOs)
  - How do you budget?
- Working with foreign payroll providers
  - Allocable to sponsored projects?
- Fringe benefit rates and overseas personnel
- Applying federal award policies to foreign personnel (compliance, timekeeping)
- Procurement/purchasing abroad
  - Can the institution's procurement policy apply abroad?
  - Is it even practical?
- Getting funds into the field
- Accounting for exchange rate fluctuation

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Clinical Research Complexities

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Compliance with the Common Rule – 45 C.F.R. Part 46

- Revised Common Rule regulations released on January 19, 2017
  - The rule generally took effect on January 21, 2019
- The Common Rule generally applies to research outside of the U.S. that is conducted or supported by HHS, including:
  - Federally-funded research awarded to a U.S. institution, conducted outside of the U.S.
  - Research where a non-U.S. institution is the prime awardee, or receives a subaward under a federally funded prime

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Federalwide Assurance

- ***Threshold Question for research involving a non-U.S. institution:*** is the non-U.S. institution ***"engaged"*** in research that is subject to the Common Rule?
  - If so, then the non-U.S. institution generally must sign a Federalwide Assurance (FWA) and register its IRB/Ethics Committee with OHRP (or designate another registered IRB)
  - Non-U.S. institutions typically are **"engaged"** if their employees or agents:
    - Interact for research purposes with any human subject of the research,
    - Obtain individually identifiable private information or identifiable biological specimens for research, or
    - Obtain informed consent of subjects.
- Note that a U.S. institution that is prime awardee ***will generally be considered "engaged" in the research***, even if all human subjects activities will be performed by a non-U.S. institution that is a subawardee.

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Federalwide Assurance

- Non-U.S. institutions are required to provide the same FWA as U.S. institutions (with slightly different requirements)
- Although non-U.S. institutions have an option on the FWA to select one of various international standards with which they comply (e.g., ICH E-6 Guidelines for Good Clinical Practice), they still must comply with the Common Rule.
  - "[A]ll institutions holding an OHRP-approved FWA . . . must comply with the requirements of 45 CFR part 46 . . . regardless of whether the institution marked one or more other procedural standards on the FWA form for international (non-U.S.) institutions as a standard to which the institution committed itself to comply." 71 Fed. Reg. 38,645 (Jul. 7, 2006)

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Federalwide Assurance

- Challenges for non-U.S. institutions executing an FWA
  - ***Institutional written procedures*** for the reporting of:
    - unanticipated problems involving risk to subjects;
    - serious or continuing noncompliance with applicable law or IRB requirements/ determinations; or
    - suspension or termination of IRB approval.
  - ***IRB written procedures*** for:
    - conducting IRB initial and continuing review of research, and reporting IRB findings to the investigator and the Institution;
    - determining which projects require review more often than annually, or verification from sources other than the investigator that no material changes have occurred since the previous IRB review; and
    - ensuring prompt reporting to the IRB of proposed changes in a research activity.

  See FWA for the Protection of Human Subjects – Terms, § 4(a).

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IRB/Ethics Committee Oversight and Informed Consent

- Qualification of IRB/Ethics Committee:
  - The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and **cultural backgrounds and sensitivity to such issues as community attitudes**, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
  - The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and **regulations, applicable law, and standards of professional conduct and practice**.

  See 45 C.F.R. § 46.107(a)

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IRB/Ethics Committee Oversight and Informed Consent

- Ensuring informed consent complies with the Common Rule:
  - Coercion (financial, or by providing free access to health care)
  - Therapeutic misconception
  - Legally authorized representatives and age of majority
  - Translations of ICFs (including back translation for IRB review)
  - Literacy and language barriers (even with a properly translated ICF)
  - Approaches to autonomy/consent (e.g., decision making by a family or village)
  - Meaning of a signature
  - Post-study expectations of participations and non-U.S. site/country

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Other Potentially Relevant U.S. Laws

- HIPAA and other U.S. privacy laws (federal and state)
- FDA laws (e.g., INDs and IDEs, export of investigational drugs and devices)
- NIH Grants Policy Statement
  - Section 16, Grants to Foreign Organizations, International Organizations, and Domestic Grants with Foreign Components
  - Flow down requirements (e.g., public policy requirements, written agreement)
- Other laws related to federal funding
  - PHS Policies on Research Misconduct (42 C.F.R. Part 93)
  - PHS financial COI regulations (42 C.F.R. Part 50, Subpart F)

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Other Potentially Relevant U.S. Laws

- Foreign Corrupt Practices Act and other fraud and abuse laws
- Various Agency regulation of the import/export of biological materials
  - FDA, CDC, USDA, U.S. Department of Commerce, Department of Transportation, U.S. Fish and Wildlife Services
- AAHRPP Accreditation Standard I-3
  - "The Organization's transnational research activities are consistent with the ethical principles set forth in its Human Research Protection Program and meet *equivalent levels of participant protection* as research conducted in the Organization's principal location *while complying with local laws and taking into account cultural context*."

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Potentially Relevant Non-U.S. Laws

- Consult OHRP's International Compilation of Human Research Standards:
  - General research laws
  - Drugs and devices
  - Clinical trial registries
  - Research injury
  - Privacy/data protection
  - Human biological materials
  - Genetics
  - Embryos, stem cells, and cloning

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