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# Establishing Programs Overseas

## Issues and Considerations

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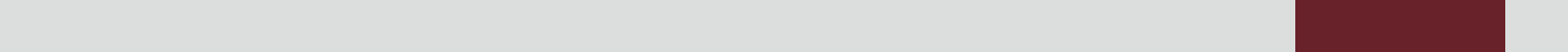
Seattle, Washington



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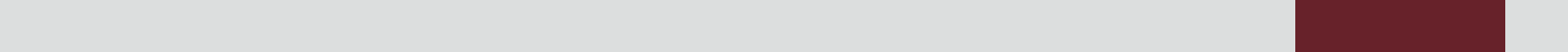
# Outline of Topics

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- Threshold Issues in Global Engagement
  - Strategy / Approach / Models
  - Registration & Legal presence overseas
  - Common Practical/Operating Issues
  - Local Law Issues
  - US Law Issues
  - Lesson's Learned
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# “Research” Abroad

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- Care and treatment for HIV-infected individuals; ARV drug delivery
  - Renovation of hospitals, clinics, and laboratories in remote locations
  - Drug industry research and development, including clinical trials
    - 33% of Phase III drug trials by US pharmaceutical industry now conducted overseas (Eastern Europe, China, Russia, India)
  - Water resources management; assembly of groundwater filtration units
  - IT infrastructure and telecommunication outfitting
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# Threshold Considerations

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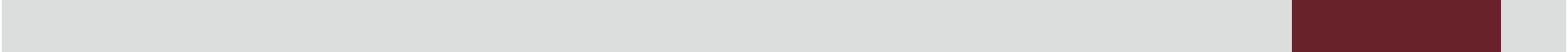


## ❖ The “Research Mission”

## ❖ Due Diligence

- Project scope; objective; location; duration; budget; source of funding; oversight; etc.
- Major players: foreign government, university, corporation, NGO, faith-based network, hospital, laboratory, clinic, etc.

## ❖ Ethical, Social, Cultural Issues

- Corruption, poor governance
  - Post-research obligations
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# Strategy & Approach

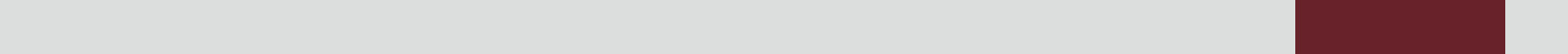
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- **Overall Approach**

- Maintaining Control/Oversight

- **Basic Models/Structures for Overseas Operation**

- Existing NGO (e.g., services agreement)
  - Local partner (e.g., subaward relationship)
  - Local incorporated entity for each country
  - Umbrella U.S. entity for all overseas research
    - Nonprofit corporation? Limited Liability Co.?
    - How much autonomy?
    - Corporate shield protection?
    - 501(c)(3) necessary?
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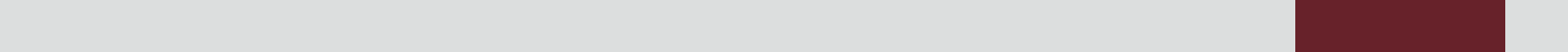
# Legal Presence Overseas

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- **Host Country Registration?**
- **Triggering Registration**
  - ❑ Opening an institutional bank account
  - ❑ Foreign employment, or assignment of personnel to overseas positions
  - ❑ Executing a lease for local office space
  - ❑ Purchasing local goods and services
  - ❑ Much more...
- **Goal: maximize privileges and exemptions**
  - Interim authorization
  - Implications of registration

# Registration Implications

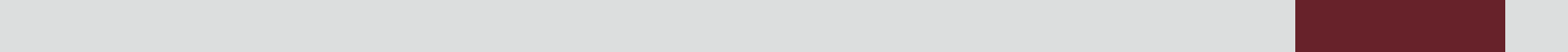
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- “Legal Presence”
    - Subject to foreign law; tax considerations, etc.
    - Obligations of institutional leadership (officers/directors)
  - Physical office requirements
  - Ongoing notification requirements
  - Annual financial statement & audit
  - Entry permits issued to foreigners
  - Notify district/state before starting project
  - Name of entity
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# Agreement with Foreign Government

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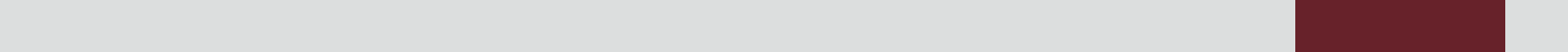
## ❖ Memoranda Of Understanding (MOU)

- Operational / symbolic agreement
  - Scope of work and obligations
  - Formal request for privileges and exemptions:
    - Examples: support for the project; assistance with government filings; access to local services
  - Direct agreement with a foreign sovereign
  - High level meetings
  - Local counsel assistance
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# Privileges & Exemptions

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## ❖ Charitable and Nonprofit Projects

- Customs duties and taxes (including VAT) on vehicles, equipment, supplies
  - Visas and work permits for expatriates
  - Assistance with credentialing medical professional
  - Ownership and disposition of assets
  - Liability protections and indemnifications
  - Extension to registered entity
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# Common Operational and Local Law Issues

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## • **Bank Account Overseas**

- Package of documents and approvals
- Host country banking regulations
- Power of attorney; control over account
- Purchasing authority for local entity

## • **Currency Exchange**

- Treatment of currency gains/losses
  - “Street” market dangers
  - Federal funds complications
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# Common Operational and Local Law Issues

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- **Foreign Taxes**

- 1) Income Taxes

- Overseas Entity

- 2) Customs/Import duties

- 3) VAT: Local Goods and Services

- Ministry of Finance exemption process?
- Point of sale vs. after-the-fact reimbursement

- 4) Property Transfer Tax



# Common Operational and Local Law Issues

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## • Foreign Employment Laws

- Applies both to local nationals and U.S. personnel assigned to positions overseas
- Basics of international employment
- “Independent Contractor trap”
- Complications of income tax withholding, local social security contributions, mandatory benefits, etc.

## • Visas

- Lawful entry ≠ lawful work
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# Regulatory/Compliance Issues

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- **Obligations To Federal Sponsors**
  - Financial compliance and cost principles
  - Property management
  - Local procurement
- **Subawards/Subrecipients**
  - Meaningful flow-down of federal sponsor obligations

# Regulatory/Compliance Issues

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## Obligations to Federal Sponsors

- **Recent “Audit of Overseas Grant Controls”**
  - Finding #1: Procurement noncompliance
    - Check procurement sources
  - Finding #2: Subrecipient Monitoring
    - Oversight and training required
  - Finding #3: Lack of documentation
    - Time and effort reporting
    - Records of taxes paid, pending exemption
    - Records retention policy

# Regulatory/Compliance Issues

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- **Human Subjects Research at foreign sites**
    - “Double whammy” of US and foreign regulations
    - Pfizer case
  - **Patient Care Issues**
    - Licensing and credentialing of health care professionals
    - Treatment of patient records; privacy
    - Storing and dispensing medications
    - Disposal of biohazards and other waste
  - **Animal Research at foreign sites**
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# Applicable US Laws

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- **Shipment of tissues/samples (biological materials)**
    - Highly regulated activity
    - USDA/CDC/Dept of Commerce Permits
  - **Export Control and Sanctions Law**
    - Make no assumptions about fundamental research exclusion
    - International Travel
  - **Antiboycott Laws**
    - Boycott participating countries: *Kuwait/Lebanon/Libya/Qatar/Saudi Arabia/Syria/United Arab Emirates/Yemen*
  - **Foreign Corrupt Practices Act (FCPA)**
    - Prohibits payments to foreign officials to influence those officials
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# Applicable US Laws - FCPA

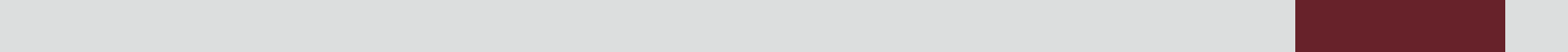
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## ➤ Misperceptions - FCPA does not apply because:

- No contact with elected government officials
  - Consider “instrumentality” of a foreign government
- No presence in the foreign country
  - Consider “willful blindness” to subawardee
- No “obtain” or “retain” any business
  - Consider “improper advantage”
- Compliance policies and procedures are voluntary
  - Consider training/education

# Learning from Others

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- **Failure to investigate overseas partners**
  - **Failure to maintain control over international venture**
    - Failure to supervise investigators and administrators
    - Failure to apply internal controls
  - **Failure to take local law into account**
  - **Failure to take U.S. law into account**
  - **Failure to gauge reliability of lead personnel overseas**
    - Who am I getting information from?
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# Contact Information

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