




Navigating International Partnerships in the UC System: A compliance Roadmap
UCOP Compliance & Audit Education Series
January 29, 2013

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Agenda

- I. Scale of the Issues
- II. What have we done at UCSF?
- III. Insurance coverage considerations
- IV. What more needs to be done?
- V. UC Foreign Affiliate office registrations

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Agenda



Scale of the Issues
Size and scope of international research at UCSF
Potential for adverse outcomes
Inefficiencies

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Size and Scope of UCSF International Research

- 199+ faculty with funded research or active CHR-approved project with an international component
- Working in more than 100+ countries (primarily in resource constrained settings)
- \$77.67M+ extramural awards received since Feb 2012 include a component conducted abroad
- More than 250 students and trainees



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Scale of the Issues: Potential for Adverse Outcomes

- Natural and political disasters (Ebola outbreak in Uganda, post-election riots in Kenya)
- Illness and trauma (medical care in resource limited settings, evacuation, notification of UCSF leadership, family, etc.)
- Charges of research misconduct (ethics of research vs. standards here, informed consent challenges)
- Violation of laws there or policies here (hiring foreign staff, banking and other funding transactions)



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Scale of the Issues: Inefficiencies

- Multiple UCSF Departments working in the same site without coordination (travel, staff, etc.)
- Many sites used for similar projects, even in the same country
- Multiple systems used for similar tasks (data collection, etc.)
- Questions of faculty oversight of UCSF trainees. UCSF faculty privileges at other sites vs. UCSF status of local faculty members



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What have we done at UCSF?



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What Have We Done? 1.

- Research policy review for UCSF's Research Administration Board (RAB - committee of faculty and senior managers reporting to the Executive Vice Chancellor for Research)
- Risk management actively engaged in providing services (travel insurance, email alerts, post-exposure prevention management)
- Convened the International Research Advisory Council (IRAC) across all schools and disciplines

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What Have We Done? 2.

The UCSF International Projects Database:
Provides access to public information; facilitating collaboration, communication, expertise, and development of new proposals.
Current awards of UCSF global researchers through July 2012
Data feeds to Profiles, plans for automation of data capture with new central systems rollout in 2013



Example of search result:

Richard Pevsner, PhD, PhD Professor
Department - Immunology

Keywords
Health Services Research, Immunology, Infectious Diseases, Immunology, Immunology, Immunology

Education
Harvard Medical School, Ohio State University, Johns Hopkins University, Stanford University, South African Research Chair in HIV, Immunology, Immunology, Immunology

Ongoing Projects
Project: Global Health and Equity - Immunology
Department: Immunology
Department: Immunology
Date: 12/12/2012
Date: 12/12/2012
Project: Global Health and Equity - Immunology
Department: Immunology
Department: Immunology
Date: 12/12/2012
Date: 12/12/2012

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What Have We Done? 3.

Global Research Consulting: Launched July 2011. One hour of free consultation. Predominantly enquires regarding international grants administration and policy.

What have We done? 4.

GlobalResearch Forum: Launched April 2012. An online moderated forum for global health research interest groups.

Agenda

Insurance Coverage Considerations

Insurance Coverage Considerations for International Research

- What is the “foreign liability” policy and what does it cover?
- How should insurance coverage presented by foreign entities in compliance with BUS-63 requirements be assessed?
- When is foreign clinical trials coverage needed?
- Other issues...

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Foreign Liability

UCOP provides foreign liability insurance for all the University’s operations outside the USA. Primary goals:

- *Avoid duplication of coverage or gaps in coverage*
- *Eliminate premium costs to the department*
- *Provide policy and claims coordination*
- *Ensure UC compliance with all foreign laws*

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Evaluating Foreign Entity Insurance Coverage

Foreign entities or organizations entering into contracts with UC must comply with BUS-63 requirements that they carry general liability coverage. However:

- Some entities do not carry insurance limits that would be expected in the USA
- Some country’s insurance markets do not offer the type of general liability coverage that is standard in USA
- Currency conversion can complicate assessment of foreign coverage



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Clinical Trials in Foreign Venues



A **Human Clinical Trial liability policy** may be required under national insurance regulations for trials conducted abroad. EU countries have compulsory liability coverage requirements for Clinical Trials in addition to many in the developing world.

- Typically, trial coverage must be purchased from an insurer domiciled in the country (an “admitted carrier”)
- Required terms and conditions vary from country to country
- Policy summaries may only be available in the language of the country where the coverage is purchased
- May be required to purchase coverage for foreign clinics or health facilities who partner with UCSF to conduct trial

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Other Foreign Insurance Considerations

- **Hiring any local nationals to work for you as employees?** Must evaluate whether the workers’ compensation and employer’s liability benefits cover them in the country where you are hiring the employee
- **Leasing or purchasing office or research space?** UC may be required to procure a general liability policy in the country where you are operating
- **Leasing or purchasing an automobile?** Must purchase compulsory automobile liability insurance from the automobile leasing company or from a local insurer

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What more needs to be done?

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What More Needs to be Done? 1.

- Follow-up on initial RAB policy analysis
 - » Continue to identify relevant policies governing global health research and educational activities reviewing policies and policy gaps to facilitate work in medium and lower income countries including:
 - » Finalizing policy on post-exposure prophylaxis for UCSF employees (and foreign staff members working on UCSF projects?)
 - » Develop policies and procedures for UC foreign affiliate operations
 - » Define banking/financial policies and guidelines for registered entities
 - » Define policies re: shipping specimens to US vs. research performed in-country
 - » Review and develop policies for UCSF personnel working abroad
 - » Review and develop policies for hiring foreign nationals working for UCSF abroad

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What More Needs to be Done? 2.

- Monitor OE pre-ward teams with extensive global research experience to evaluate efficiency, effectiveness compared to similar grants by other teams
- Provide more effective training of research personnel here and abroad in support of active research projects
- Improve tracking of grants, multiple PI's and specific sites (city, hospital, etc., not just country)
- Better integrate research and educational activities given similar policy applications

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What More Needs to be Done? 3.

The Global Resource HUB: Uses new and existing data as a central resource for researchers, program staff working abroad and international visiting scholars. Goal is to provide tool set designed specifically for the elimination of barriers for the global researcher.

Global Resource HUB

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Global Resource HUB

Global Research Enterprise Support (G-RES) Website
INFORMATION ARCHITECTURE - TOP LEVEL

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What More Needs to be Done? 4.

- Provide a One Stop Shop for UCSF International Activities from pre-award to project close out – including project management
- Experts **here** helping to facilitate the work **there**, including:
 - » Maintaining accurate and current database of resources here and in-country available for research support
 - » Compliance (both ethical and fiscal)
 - » Data collection, sharing, and analysis
 - » Capacity building (for research, education, and research administration and management)
 - » Support for educational placement and supervision of UCSF students, residents, trainees

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UC Foreign Affiliate Offices

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UC Foreign Affiliate Offices: what are they

- Legal UC entity adhering to the laws of the local country while also maintaining compliance UC policies and officially reporting to UC designees (for UCSF delegation has been granted to the Chancellor)
- Allows legal ability to lease space, hire local employees, provide work permits for UCSF employees
- Delegated authority to open a local bank account
- Ability to setup an official UC office to support UCSF international activities (potentially able to support other UC campus international activities)
- Currently UCSF is approved to establish offices in PEPFAR countries in Africa

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UC Foreign Affiliate Offices: where are we

- The first UC foreign affiliate office has been registered by UCSF in Tanzania (registered as Global Programs), we are currently submitting required paperwork for registration in Kenya (Global Programs for Research and Training)
 - » Next steps for Global Programs in Tanzania include opening a bank account, establishing office policies and procedures – making the office operational (leveraging work already done by ITECH and others in Tanzania)
 - » Next steps for Global Programs for Research and Training in Kenya, submit required paperwork (will take 4 to 6 months for registration); partnering with FACES program to develop operations policies and procedures
 - » For both offices develop policies, processes and practices for hiring and managing local staff – balance between local laws and UC personnel policies.

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