Navigating International Partnerships in	
the UC System: A compliance Roadmap  UCOP Compliance & Audit Education Series	
January 29, 2013	
UCSF GLOBAL HEALTH SCIENCES Improving health and reducing inequities worldwide UCSF	
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	
2	
UCSF GLOBAL HEALTH SCIENCES Improving health and reducing inequities worldwide	
Agenda	
Scale of the Issues	
Size and scope of international research at UCSF Potential for adverse outcomes	
Inefficiencies	
3	
UCSF GLOBAL HEALTH SCIENCES Improving health and reducing inequities worldwide	

# Size and Scope of UCSF International Research

- 199+ faculty with funded research or active CHRapproved 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 aboard
- More than 250 students and trainees



# 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)



# UCSF

### 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





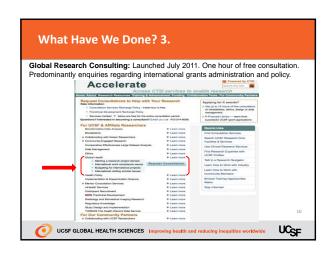
Agenda	
What have we done at UCSF?	
	7
UCSF GLOBAL HEALTH SCIENCES Improving health and reducing inequities worklyide	UCSF

### What Have We Done? 1.

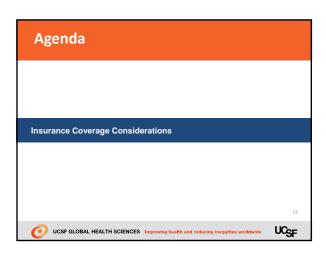
- Research policy review for UCSF's Research
   Administration Board (RAB committee of faculty and
   senior managers reporting to the Executive Vice
   Chancellor for Research)
- Risk management actively engaged in providing services (travel insurance, email alerts, post-exposure prevention management)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











# **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...

UCSF GLOBAL HEALTH SCIENCES Improving health and reducing inequities worldwide

# **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

UCSF GLOBAL HEALTH SCIENCES Improving health and reducing inequities worldwide

# UCSF

UCSF

# **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

UCSF GLOBAL HEALTH SCIENCES Improving health and reducing inequities worldwide



# **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



UCSF GLOBAL HEALTH SCIENCES Improving health and reducing inequities worldwide



## 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



UCSF GLOBAL HEALTH SCIENCES Improving health and reducing inequities worldwide



# **Agenda** What more needs to be done? UCSF GLOBAL HEALTH SCIENCES Improving health and reducing inequities worldwide UCSF

### 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

UCSF GLOBAL HEALTH SCIENCES Improving health and reducing inequities worldwide



### 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

UCSF GLOBAL HEALTH SCIENCES Improving health and reducing inequities worldwide



# 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.

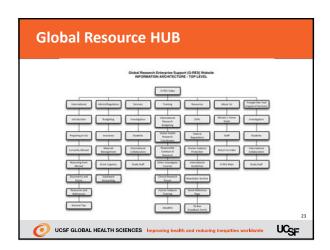












# What More Needs to be Done? 4. Provide a One Stop Shop for UCSF International Activities from pre-award to project close out – including project management Experts here helping to facilitate the work there, including: Maintaining accurate and current database of resources here and in-country available 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

Agenda	
UC Foreign Affiliate Offices	
UCSF GLOBAL HEALTH SCIENCES Improving health and reducing inequities worldwide	
UC Foreign Affiliate Offices: what are they	
<ul> <li>Legal UC entity adhering to the laws of the local country while also maintaining compliance UC policies and officially</li> </ul>	
reporting to UC designees (for UCSF delegation has been granted to the Chancellor)	
<ul> <li>Allows legal ability to lease space, hire local employees, provide work permits for UCSF employees</li> <li>Delegated authority to open a local bank account</li> </ul>	
<ul> <li>Ability to setup an official UC office to support UCSF international activities (potentially able to support other UC</li> </ul>	
campus international activities)  • Currently UCSF is approved to establish offices in PEPFAR countries in Africa	
UCSF GLOBAL HEALTH SCIENCES Improving health and reducing inequities worldwide	
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.	
UCSF GLOBAL HEALTH SCIENCES Improving health and reducing inequities worldwide	