

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO  
AUDIT AND ADVISORY SERVICES**

**International Research Review  
Project #17-049**

**August 2017**

University of California  
San Francisco



**Audit and Advisory Services**

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**SUBJECT: International Research Review**

As a planned internal audit for Fiscal Year 2017, Audit and Advisory Services (“A&AS”) conducted a review of International Research activities at UCSF. Our services were performed in accordance with the applicable International Standards for the Professional Practice of Internal Auditing as prescribed by the Institute of Internal Auditors (the “IIA Standards”).

The preliminary draft report was provided to department management in June 2017. Management provided us with their final comments and responses to our observations in August 2017. The observations and corrective actions have been discussed and agreed upon with department management and it is management’s responsibility to implement the corrective actions stated in the report. In accordance with the University of California audit policy, A&AS will periodically follow up to confirm that the agreed upon management corrective actions are completed within the dates specified in the final report.

This report is intended solely for the information and internal use of UCSF management and the Ethics, Compliance and Audit Board, and is not intended to be and should not be used by any other person or entity.

Sincerely,

A handwritten signature in black ink, appearing to read 'Irene McGlynn', is written over a light blue horizontal line.

Irene McGlynn  
Director, UCSF Audit and Advisory Services

## EXECUTIVE SUMMARY

### I. BACKGROUND

As a planned audit for Fiscal Year 2017, Audit and Advisory Services (A&AS) completed a review of the current governance structure, controls and processes in place for conducting international research activities at the University of California, San Francisco (UCSF) within central units and schools.

To fulfill its mission of advancing health worldwide, UCSF engages in a number of international biomedical research activities. UCSF has 323 active global health-related research projects being conducted by 147 investigators in 144 countries<sup>1</sup>. International research poses unique risks in that projects are governed by the laws and customs of both the United States and the host country where the research takes place. Additionally, they may be regulated by a variety of U.S. and internationally-based government codes and agencies. Distribution of funds, ability to receive funds and ability to maintain project working capital, as well as hiring of staff, may also be dependent on the economic and political climate of the host country, thus requiring specialized knowledge and management skills.

International research is conducted within UCSF's graduate and professional schools, who work around the world to train global health leaders, and to advance the University's mission of advancing health worldwide through helping governments and organizations improve their health systems, and build sustainable solutions to improve health and eliminate disease.

Due to the complexities and variety of activities involved in international research administration and related matters, support for international projects occurs in many departments throughout the University, including:

- Office of Sponsored Research (OSR), which performs an initial risk assessment of award subrecipients and annual re-evaluations as well as executes subrecipient research agreements and subsequent amendments on behalf of the University;
- The home department of the lead Principal Investigator (PI), which manages day to day project administration and oversight, and PI support;
- Contracts & Grants Accounting (CGA), which manages post-award invoice payments and funds transfers; and
- Risk Management (RM), which is involved in insurance related services.

In 2005 UCOP published guidelines for the establishment and operations of foreign affiliate organizations and foreign operations established to support the University's teaching, research and public service missions. Additionally, an updated presidential policy on International Activities was issued in June 2017. UCSF Campus Administrative Policy 100-10, "Affiliation Agreements", establishes guidelines and responsibilities for entering into affiliation agreements between UCSF and other institutions.

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<sup>1</sup> Per Global Health Sciences: Global Research Projects Interactive Map as of July 2017, <http://globalprojects.ucsf.edu/map>

UCSF Global Health Sciences (GHS) received delegated authority in 2011 from the UC Office of the President (UCOP) to establish foreign program offices in 19 African countries that are part of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Currently, UCSF has registered foreign offices in six of the PEPFAR countries.<sup>2</sup>

## II. AUDIT PURPOSE AND SCOPE

The purpose of this review was to assess processes, procedures, and controls in place for the management of international research within departments. The scope of the review included processes and procedures to determine whether:

- The risk assessment processes for international subrecipients are effective,
- There is a clear separation between UCSF and the subrecipient non-governmental organizations (NGOs),
- There is an effective strategic and operational governance structure for the oversight of international research activities,
- International research is in compliance with University and UCSF policies,
- Departments exercise appropriate oversight and financial controls for their international research projects,
- Subrecipient agreements are properly executed and approved, and
- Subrecipient technical and financial reporting are submitted as required.

The scope of our review included all international subawards active as of November 1, 2016. The focus of the review was on awards managed within UCSF's professional schools; therefore, awards managed by GHS were excluded. Additionally, we specifically excluded subawards with the Kenya Medical Research Institute (KEMRI), as known issues with this entity are currently being addressed.

We obtained a list of international subawards active as of November 1, 2016 from across schools and departments. From the list, we judgmentally sub-selected a sample of 11 studies based on the following criteria and discussions with key stakeholders:

- a. By country – focusing on less developed countries as risks are higher due to less established infrastructure and administrative processes. Based on preliminary discussions with selected individuals (listed on page 3-4), EU countries were excluded because of lower risks
- b. By School; and Department – ensuring that at least one project was selected for each professional school (except for School of Dentistry which has limited international research portfolio)
- c. Expenditure amount of the award – For SON, SOP and Cancer Center, we selected programs with the highest expenditures; for SOM, a cross section of award expenditures were selected with 2 studies over \$1M; 5 studies between \$200K - \$1M and 1 study under \$50K.

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<sup>2</sup> The countries include Kenya, Namibia, South Africa, Tanzania, Uganda and Mozambique,

The studies reviewed are listed below:

Department	School	Country	Subcontractor
Epidemiology & Biostatistics	SOM	Uganda	Infectious Diseases Institute (IDI)*
HDF CCC	Cancer Center	Uganda	Infectious Diseases Institute (IDI)*
Laboratory Medicine	SOM	South Africa	South African National Blood Service
Med AIDS/HIV	SOM	Uganda	Infectious Disease Research Collaboration (IDRC)**
Department of Medicine	SOM	South Africa	Anova Health Institute
Pulmonary SFGH	SOM	Vietnam	National Lung Hospital (Vietnam)
Neurology	SOM	Thailand	SEARCH / Thai Red Cross AIDS Research
Ob/Gyn	SOM	Lebanon	Arab Foundation for Freedoms and Equality
Ob/Gyn	SOM	Zimbabwe	College of Health Sciences (University of Zimbabwe) - UZ-UCSF Research Collaboration Programme
Family Health Care Nursing	SON	Guatemala	Universidad del Valle de Guatemala
Clinical Pharmacy	SOP	Uganda	Infectious Disease Research Collaboration (IDRC)**

\* IDI was selected for Cancer Center and Epidemiology due to size of the awards and it was the only award for the Cancer Center in a PEPFAR country. These are two different studies with IDI.

\*\* IDRC was selected as a sample for SOM since it is a long-term collaborative program with numerous subawards activities and it was the only significant project for SOP. These are two different studies with IDRC.

The studies listed above were judgmentally selected based on the exclusions and specific criteria mentioned in previous paragraphs and may not be as broadly represented.

### III. PROCEDURES PERFORMED

To conduct our review, the following procedures were performed for the areas in scope:

- Reviewed UC system wide and UCSF local policies for international activities to understand the requirements of this activity,
- Reviewed the risk assessment process for international subrecipients and assessed its effectiveness and whether appropriate mitigation plans are in place
- Reviewed international research related agreements for compliance with UC and regulatory guidelines,

- Reviewed technical and financial reporting from the subrecipient for compliance with the requirements of subaward agreements,
- Assessed the processes and controls for financial and compliance monitoring
- Reviewed formation document and relationships for two foreign non-governmental organizations, specifically:
  - Infectious Diseases Research Collaboration (Uganda), and
  - UZ-UCSF Collaborative Research Program (Zimbabwe),
- Assessed whether current governance structure for supporting international research adequately addresses the needs of the university and mitigates the inherent risks of this activity.

As part of the review we interviewed relevant personnel within schools, departments and central offices to understand their processes and procedures for the management of clinical research performed abroad including but not limited to:

- Assistant Controller, Contracts and Grants Accounting
- Deputy Director, Global Health Sciences
- Deputy Campus Counsel, Office of Legal Affairs
- Director, Risk Management and Insurance Services
- Director, Research Management Services
- Interim Director, Government & Business Contracts
- Subawards Manager, Research Management Services
- Director of Finance and Administration, AIDS Research Institute, Global Health Sciences and the Department of Epidemiology and Biostatistics
- Business Manager, Bixby Center for Global Reproductive Health
- Deputy Director for Science and Administration, HIV/AIDS division of the Department of Medicine at ZSFG
- Associate Chair, Department of Obstetrics, Gynecology & Reproductive Sciences
- Division Manager, Pulmonary Division, Department of Medicine at ZSFG
- Director of Research Administration, Department of Medicine
- Director, Center for Global Health, School of Nursing
- Program Manager, Center for Global Health, School of Nursing
- Senior Financial Analyst, Department of Clinical Pharmacy, School of Pharmacy
- Associate Dean Administration & Finance, Dean's Office, School of Dentistry

Work performed was limited to the specific activities and procedures describe above. As such, this report is not intended to, nor can it be relied upon to provide an assessment of compliance beyond those areas specifically reviewed. Fieldwork was completed in June 2017.

#### **IV. SUMMARY**

Based on our work performed for the awards selected for this review, UCSF has made progress in developing infrastructure support for international research activities. The processes for executing and approving foreign subrecipient agreements and amendments were functioning well. Additionally, there was sufficient oversight and review of financial transactions and budget monitoring by PIs and department administrators.

There are opportunities for UCSF to improve on processes and observations from the review are summarized in the “Observations and Management Corrective Actions” section that follows.

- Two of the 11 studies reviewed did not have the necessary affiliation agreements in place
- One UCSF international program, while not a registered legal entity, has created conditions that can be perceived as UCSF operating in a foreign country.
- There is insufficient guidance regarding the use of third party partners in countries where Non-governmental Organizations have already been established by UCSF, or where other third party facilitating organizations routinely work.
- UCSF’s strategic and operational governance structure for the oversight of international research activities could be enhanced.
- Risk assessments of foreign subrecipients do not adequately address the risks associated with these international collaborations.
- International research activities are not always vetted through UCSF Risk Management and Insurance Services for insurance requirements.

**OBSERVATIONS AND MANAGEMENT CORRECTIVE ACTIONS (“MCA”)**

<b><u>No.</u></b>	<b><u>Observation</u></b>	<b><u>Risk/Effect</u></b>	<b><u>Recommendation</u></b>	<b><u>Management Action Plans</u></b>
1	<p><b><i>Two of the 11 studies reviewed did not have the necessary affiliation agreements in place.</i></b></p> <p>We noted that Affiliation Agreements or other legal agreements are not always in place for research collaborative programs undertaken abroad. Additionally, there is lack of understanding on the ownership for drafting, approving, and reviewing of such agreements as well as monitoring to ensuring that these agreements exist and sufficiently protect the university.</p> <p>In our review of 11 studies, there were three programs that required affiliation agreements. We identified one case where agreement was not in place (UZ-UCSF) and another case where the agreement (IDRC) did not sufficiently reflect the actual activities being conducted:</p> <p>The Department of Obstetrics and Gynecology, Zuckerberg San Francisco General (OB/GYN ZSFG) established a collaborative research program with the University of Zimbabwe in 1994. In October 2003, a Memorandum of Understanding (MOU) (with a term of five years) was signed to document both institutions’ desire to establish a research partnership to strengthen the scientific exchange between them. In 2007 a Clinical Trials Unit was created named University of Zimbabwe-University of California San Francisco Collaborative Research Programme (UZ-UCSF). Other than the MOU (which</p>	<p>Conduct of foreign operations without appropriate assessment, review, and approval of contractual arrangements by the University may lead to UCSF taking on unknown or unanticipated risks.</p>	<p>a) The department of OB/GYN ZSFG and HIV, ID and GM Division at ZSFG should work with the EVCP and Campus Legal Counsel to create appropriate affiliation agreements to formalize the research collaborations and clearly define the roles, responsibilities, and liabilities of each entity.</p> <p>b) The processes for drafting, approving, and retaining international affiliation agreements should be clarified and communicated to relevant parties in the campus. Additionally, the</p>	<p>a) OB/GYN ZSFG will develop an affiliation agreement with the University of Zimbabwe</p> <p><b>Responsible Party:</b> OB/GYN ZSFG Division Chief</p> <p><b>Target Date:</b> September 30, 2017</p> <p>b) HIV, ID &amp; GM Division at ZSFG will determine whether a separate agreement is required with IDRC or to update the existing affiliation agreement with the University of Makerere to include IDRC</p> <p><b>Responsible Party:</b> HIV, ID &amp;GM ZSFG Division Chief</p> <p><b>Target Date:</b> November 30, 2017</p>

<u>No.</u>	<u>Observation</u>	<u>Risk/Effect</u>	<u>Recommendation</u>	<u>Management Action Plans</u>
	<p>expired in 2010) no other signed agreement could be located to document the affiliation between UZ and UCSF.</p> <p>Additionally, the HIV, Infectious Disease and Global Medicine (HIV, ID &amp; GM) Division at ZSFG works with an independent NGO in Uganda, the Infectious Diseases Research Collaboration (IDRC), which is affiliated with Makerere University. UCSF has an affiliation agreement with Makerere University in Uganda, but this agreement is not specific to IDRC nor reflects the actual activities conducted</p>		<p>responsibility for monitoring that these agreements exist needs to be identified and assigned to an appropriate unit.</p>	<p>c) Templates for Affiliation Agreements will be made available on the EVCP website  <b>Responsible Party:</b> EVCP Office   <b>Target Date:</b> January 31, 2018</p> <p>d) A meeting to be held with appropriate stakeholders to update the International Agreements Matrix and related materials on the EVCP website   <b>Responsible Party:</b> EVCP   <b>Target Date:</b> March 31, 2018</p> <p>e) A list of current affiliation agreements will be made available on the web on a periodic basis, at least quarterly. This will involve an investment and modification of the Salesforce site where</p>

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				<p>many affiliations are currently logged.</p> <p><b>Responsible Party:</b> EVCP, working with Government, Business Contracts and Grants</p> <p><b>Target Date:</b> August 30, 2018 – pending identification of funding</p>
2	<p><b><i>One UCSF international program, while not a registered legal entity, has created conditions that can be perceived as UCSF operating in a foreign country.</i></b></p> <p>During our review, it was noted that the UZ-UCSF Research Collaborative Program, while not a registered legal entity, has created conditions that can be considered as a UCSF presence in the foreign country that may have created unanticipated financial and reputational risks and liabilities for UCSF as follows:</p> <ul style="list-style-type: none"> <li>The founding member (and Executive Director of UZ-UCSF) holds dual appointments at UZ and UCSF. At UCSF he is a salaried employee (Academic Coordinator III) and the Principal Investigator (PI) for the NIH award that has UZ as its subrecipient. As UZ-UCSF Executive Director he has management oversight responsibility</li> </ul>	<p>There may be unknown or unanticipated risks that need to be identified, assessed and prioritized based on the level of risk.</p>	<p>a) OB/GYN ZSFG program management should engage a local legal counsel (with the assistance of the UCSF Office of Legal Affairs) to discuss the current administrative structure of the research collaborative to determine an appropriate risk remediation plan to mitigate UCSF's risk from prior operational organization and</p>	<p>a) OB/GYN ZSFG management will request the University of Zimbabwe legal counsel to conduct an assessment of the current administrative structure of the research collaboration and determine an appropriate risk remediation plan to mitigate UCSF's risk from prior operational organization and activities.</p> <p><b>Responsible Party</b> OB/GYN ZSFG Division Chief</p>

<u>No.</u>	<u>Observation</u>	<u>Risk/Effect</u>	<u>Recommendation</u>	<u>Management Action Plans</u>
	<p>including signature authority on the UZ-UCSF bank accounts and has signed lease contracts on behalf of UZ-UCSF. This dual role of the Executive Director may create institutional conflict of interest.</p> <ul style="list-style-type: none"> <li>• There has been use of UCSF’s name and seal on UZ-UCSF’s website, policies and employment contracts, and audited financial statements. Unauthorized use of UCSF’s name and seal on UZ-UCSF’s website, policies and employment contracts is a violation of University Policy<sup>3</sup>.</li> <li>• As a formal agreement was not in place, UCSF’s operations in Zimbabwe would not have been rolled under UC’s foreign liability coverage.</li> </ul> <p>Additionally, an UCSF employee is working in Uganda at Infectious Diseases Research Collaboration (IDRC) for extended periods of time on projects funded by federal awards. These circumstances may create a potential tax liability and filing obligation to Uganda for UCSF, the employee and/or IDRC.</p>		<p>activities.</p> <p>b) OB/GYN ZSFG Program managers should work with UZ to:</p> <ul style="list-style-type: none"> <li>• Remove the UCSF PI from authority on bank accounts and lease contracting</li> <li>• Remove the UCSF name and logo from all UZ documents.</li> </ul> <p>c) Consider performing an assessment of the potential tax liability for UCSF and/or the employee.</p> <p>d) Key risks and resources for other UCSF international programs, especially those that are large and long-standing, should be identified along with guidelines and</p>	<p><b>Target Date</b> Completed.</p> <p>b) OB/GYN ZSFG management will review the assessment by University of Zimbabwe’s counsel with UCSF legal counsel.</p> <p><b>Responsible Party</b> OB/GYN ZSFG Division Chief</p> <p><b>Target Date</b> November 1, 2017.</p> <p>OB/GYN ZSFG management has initiated the removal of UCSF name on all UZ documents and agreements and PI as a signatory on bank accounts.</p> <p><b>Responsible Party:</b> OB/GYN ZSFG Division Chief</p> <p><b>Target Date:</b> Completed.</p>

<sup>3</sup> Campus Administrative Policy 050-13

<u>No.</u>	<u>Observation</u>	<u>Risk/Effect</u>	<u>Recommendation</u>	<u>Management Action Plans</u>
			resources to address risk as appropriate.	c) Division of HIV, ID & GM ZSGH management will work with Contracts & Grants Unit and Payroll within the Campus Controller's Office to determine UCSF's and the employee's tax payment and filing obligations  <b>Responsible Party:</b> HIV, ID & GM ZSFG Division Chief  <b>Target Date:</b> November 30, 2017  d) See management action plans in observation #4
3	<p><b><i>There is insufficient guidance regarding the use of third party partners in countries where Non-governmental Organizations (NGOs) have already been established by UCSF, or where other third party facilitating organizations routinely work.</i></b></p> <p>UCSF collaborates with partners in host countries to help fulfill its objective of building research capacity in these nations. UCSF has also established its own organizations to help mitigate the risk of non-compliance with non-US laws. For instance, a UCSF</p>	Global offices or third-party facilitating organizations can mitigate and manage risk by providing a compliant, shared operational support structure monitored by UCSF	Consider developing guidelines to lay out the functions and services that are appropriate for UCSF's established NGOs or other third party facilitating organizations to provide. This would allow PIs to work with	EVCP, GHS, Compliance, Risk Management, Legal, and UCOP as appropriate will work on refining the guidelines published on UCGo.org website on the use of services provided by third party partners and those appropriate for in-house NGOs.

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	<p>non-governmental organization (NGO) has been established in Uganda to reduce potential University liability by supporting compliance with local laws and regulations among other benefits. Another NGO in Uganda, the Infectious Diseases Research Collaboration (IDRC) is used by multiple UCSF departments (SOM AIDS-ZSFG and SOP Clinical Pharmacy) for their international research projects. UCSF has not defined guidelines wherein the NGO developed in-house or other facilitating partners should be used.</p>	<p>stakeholders.</p>	<p>appropriate parties and help ensure that international research is conducted in a compliant manner.</p>	<p><b>Responsible Party:</b> EVCP, with Global Health Sciences, Compliance, Risk Management, and Legal.</p> <p><b>Target Date:</b> August 30, 2018</p> <p>Research Management Services will assist in data collection (See management action plans in observation #4)</p> <p><b>Responsible Party:</b> Office of Sponsored Research</p> <p><b>Target Date:</b> November 30, 2017 for data and survey collection</p>
<p>4</p>	<p><b><i>UCSF’s strategic and operational governance structure for the oversight of international research activities could be enhanced.</i></b></p> <p>The management structure for the GHS African NGO (Global Programs) has been established with an appointed Technical Advisory Group (TAG). The TAG is also available to the Chancellor and EVCP, but additional key governance or resource elements for international research should be provided to</p>	<p>Absence of an effective strategic governance structure may result in international activities not being aligned with the campus’ mission. Additionally, the pursuit of potential</p>	<p>UCSF should develop a steering committee to look at strategic goals, and to set priorities.</p> <p>Information should be gathered on key risks, available guidelines, educational programs,</p>	<p>a) EVCP Office will coordinate appropriate stakeholders for a steering committee to set strategic goals, priorities and plans for managing key risks.</p> <p>b) Information already gathered from key</p>

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	<p>various campus groups. These could include:</p> <ul style="list-style-type: none"> <li>• A high level steering committee to look at strategic goals and guiding principles for international partnerships.</li> <li>• Guidelines to identify key risks, how they are mitigated and tracked. (Also see number 3)</li> <li>• Additional guidance and educational programs for faculty and staff that conduct and administer research abroad. This includes an effective mechanism for ensuring appropriate subject matter expertise resources are available and well communicated to departments.</li> </ul>	<p>international partners may not be effectively coordinated among schools or departments.</p>	<p>and expert resources for faculty, staff, and trainees engaged in international research and partnerships. This information should be presented to key stakeholders for further evaluation and planning.</p>	<p>stakeholders will be reviewed to identify the stakeholders' views on key risks, as well as needs for guidelines (including the use of in-country services provided by third party partners and those appropriate for in-house NGOs), educational programs and subject matter expertise resources for those engaged in international research at different levels. A follow-up survey on perceived risks and needs will be sent to the Technical Advisory Group (TAG) members, as well as the Vice-deans for research at each school, which they will forward to appropriate PIs and departmental program managers most involved in international research. A summary report will be put together for presentation to</p>

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				<p>appropriate stakeholders (such as the EVCP, Compliance, Risk Management, GHS and Legal) who will together evaluate this needs assessment and future actions.</p> <p><b>Responsible Party:</b>                      a) EVCP                       b) EVCP, Audit &amp; Advisory Services, Compliance, Risk Management, GHS, &amp; Legal</p> <p><b>Target Date:</b>                      August 30, 2018</p>
<p><b>5</b></p>	<p><b><i>Risk assessments of foreign subrecipients do not adequately address the risks associated with international collaborations.</i></b></p> <p>From our review of OSR’s subcontract Risk Assessment review process, we noted that:</p> <ul style="list-style-type: none"> <li>• The Subrecipient Questionnaire has not been modified to be specific for foreign subrecipients.</li> <li>• Financial and operating risks of the host country are not assessed. Up until December 2016, sanction status was not identified.</li> <li>• There is no examination of the legal status of the subcontractor in the host country.</li> <li>• Financial policies and procedures are not</li> </ul>	<p>International research collaborators present risks not associated with domestic collaborators. UCSF may not be able to effectively mitigate these risks without an appropriate evaluation of them.</p>	<p>The Risk Assessment process should be evaluated and updated to tailor for International Agreements</p>	<p>OSR management is in the process of revising its Risk Assessment methodology to include country, institution and project level risks. The revised policies and procedures will be developed and implemented.</p> <p><b>Responsible Party:</b>                      Director of Office of Sponsored Research</p>

<u>No.</u>	<u>Observation</u>	<u>Risk/Effect</u>	<u>Recommendation</u>	<u>Management Action Plans</u>
	requested.			<p><b>Target Date:</b> October 31, 2017</p>
6	<p><b><i>International research activities are not always vetted through UCSF Risk Management and Insurance Services for insurance requirements.</i></b></p> <p>General liability insurance standard terms and conditions (often called “public liability” in foreign countries) and requirements vary by each foreign host country. UC carries foreign general liability coverage to cover risks associated with its operations overseas. But for coverage to apply, affiliation agreements must be reviewed/approved by Risk Management prior to commencement of operations.</p> <p>UC also requires that all foreign entity partners have adequate general (public) liability insurance coverage in place to cover risks associated with their operations under the agreement. Departments are not always aware of these requirements and may enter into affiliation agreements without adequate coverage in the absence of Risk Management review.</p> <p>Additionally, clinical trials insurance, a separate and distinct form of coverage from general (public) liability which provides coverage in the event that a human subject is injured in the course of a clinical trial, is not consistently managed across UCSF. Such coverage is mandatory under regulations in many countries.</p> <p>In our review we found that UC’s foreign liability coverage would not have extended to cover UCSF’s</p>	<p>Without an adequate review of affiliation agreements or clinical trial agreements by Risk Management, UCSF may not be effectively mitigating the risks associated with international research operations through appropriate insurance coverage.</p>	<p>a) Any future written agreements with UZ should be reviewed by Risk Management to assure that appropriate insurance coverage and indemnification provisions are in place.</p> <p>b) Regular communication to the research community should stress awareness of risks inherent in conducting overseas research and insurance requirements for international clinical trials through consultation with Risk Management.</p>	<p>a) OB/GYN ZSFG when developing the affiliation agreement with the University of Zimbabwe will ensure that Office of Risk Management reviews the insurance provisions</p> <p><b>Responsible Party:</b> OB/GYN ZSFG Division Chief</p> <p><b>Target Date:</b> September 30, 2017</p> <p>b) Office of Sponsored Research in collaboration with Risk Management will develop and send out regular communication to the research community on the awareness of risks inherent in conducting overseas research and insurance requirements for</p>

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	<p>operations in Zimbabwe because the UZ-UCSF Collaboration was never formally constituted nor was a formal agreement in place between UZ and UCSF spelling out the insurance requirements. Since clinical trials were being conducted, additional coverage (outside of foreign general liability) should likely have been purchased as well.</p>			<p>international clinical trials</p> <p><b>Responsible Party:</b> Director of Office of Sponsored Research</p> <p><b>Target Date:</b> October 31, 2017</p>