Guidance for International Research Activities affected by COVID-19 Pandemic – March 19, 2020

Overview

As the COVID-19 pandemic situation develops globally, UCSF faculty, staff, and partners should expect significant disruption of planned research and training activities abroad. The following guidance has been issued by the Office of Research for UCSF faculty and staff planning or implementing UCSF research projects abroad.

First and foremost, UCSF projects and offices implemented abroad are governed by the host-country laws and parameters set by our local collaborating partners. While UCSF offers the following guidance for researchers in response to COVID-19, these may be superseded by local mandates intended to protect the health and safety of the population.

Secondly, this situation is continually evolving and information will updated as it becomes available – please routinely check the Resource links at the end of the document including UCSF COVID-19 Guidance for Researchers for updates and further guidance.

UCSF employees based internationally

- The U.S. State Department is set to announce a level 4 travel advisory applying to all international travel, its most serious warning. The advisory would instruct all Americans abroad to either return to the United States or prepare to shelter in place. UCSF employees currently based or traveling abroad should consult with their supervisor regarding the decision to return to their home country[1] or stay in their host country[2].
- For UCSF Global Programs for Research and Training (affiliate offices of UCSF in Kenya, Mozambique, Namibia, Tanzania and Uganda), guidance regarding international operations has been provided by UCSF International Research Support Operations (IRSO) Office. Leadership of Global Programs country offices are empowered to make operational decisions based on the evolving local situation.

Ongoing and planned research activities

- In line with UCSF campus policies for healthcare research, principal investigators and research administrators should work with their local counterparts in foreign countries to determine whether research and other activities conducted in international settings should be maintained at this time based on whether these activities are deemed essential to the health and/or well-being of the participant or patient. The UCSF Office of Research offered early guidance to make

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[1] Home country: Relating to the country of origin or permanent place of residence for an employee

[2] Host country: Relating to the country of assignment for an employee

[this determination](#) (March 11), which has recently become more stringent[3] on campus due to San Francisco's shelter in place order.

- Depending on local COVID-19 epidemiology, principal investigators may consider whether activities should be converted to being conducted remotely.[4] Research visits that cannot be performed remotely and have not been deemed essential to a participant's health and/or well-being should be considered for postponement.
- In-person meetings and other group gatherings should move to virtual teleconferencing, wherever feasible, to avoid group exposure and transmission.
- At this point, there is a lack of clarity on the impact that this suspension of activities will have on contract and grant agreements and the current setup of research and administrative infrastructure in foreign countries. Further communication will be provided as it becomes available.

Travel

- UCSF is restricting all non-essential university-sponsored travel, both domestic and international, until further notice.
- All intra-country, work-related travel should be limited for only essential activities being maintained in the host-country at this time.

UCSF Institutional Review Board

- In general, changes made to research in response to a public health threat can be made without first obtaining IRB review and approval provided that the change in the research was made to eliminate apparent immediate hazards to the subject.
- Guidance from the UCSF IRB will be forthcoming, addressing missed visits, remote visits, study visits out of window, etc., as well as reporting of study deviations for the same. See [UCSF IRB COVID-19 Resources](#) for additional IRB updates and guidance.

Relationship management with research sponsor and collaborative institutions

- The Office of Research posted an [open letter](#) on March 13, 2020 to the attention of sponsors and collaborators that describes our [Interim Policy on Human Subjects-Related Research Visits at San Francisco Campuses during COVID-19 Outbreak](#) [updated March 16, 2020]. Principle Investigators should consider these policies and how they might apply in the international contexts in which they work. Principal investigators or their designees are asked to contact study sponsors and collaborators to notify them of this policy and make appropriate arrangements.
- The Office of Sponsored Research (OSR) will work with Principal Investigators on any required reporting/official letters required by Federal and other sponsors, and may reference the letter posted by the Office of Research. Additional information is posted on the [OSR website](#).

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[3] [Revised Interim UCSF Policy on Human Subjects-Related Research Visits at San Francisco Campuses during COVID-19 Outbreak](#). Effective on March 16, 2020

[4] Changing from an in-person research visit to a remote (Zoom or phone) visit does not require pre-approval from the UCSF IRB.

- The National Institutes of Health have released [Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19](#) to alert the community of administrative flexibilities applicable to NIH applicants and recipients who are conducting research activities related to or affected by COVID-19. For additional information regarding NIH's response and guidance related to COVID-19, see the [NIH topic specific site](#).

Healthcare workforce preparation and training

- For activities deemed essential to the health and/or well-being of the participant or patient and being maintained, UCSF has developed *[Guidance for Screening of Research Participants by Clinical Staff](#)* that may be useful for adaptation to local settings and be utilized for the safety of research staff and participants.
- Additional [COVID-19 clinical resources for healthcare staff](#) have been provided by UCSF Health Epidemiology and Infection Prevention. These resources can be shared and adapted to local country contexts.

Limiting patient or study participant intake and congregation

- Clinics or other sites where research is conducted may be crowded due to limited space or increased presentation of symptomatic patients due to COVID-19. To increase social distancing and reduce potential of community transmission, consider the following tactics:
  - Pre-screen and separate participants with respiratory symptoms prior to entry into the research or health facility so they are not waiting among other research participants or patients seeking care. Identify a separate, well-ventilated space that allows waiting patients and visitors to be separated.
  - Consider utilizing a well-spaced outdoor triage area for waiting participants and visitors.
  - Reduce non-essential in-person visits to clinic or study site. If enrolled patients or study participants require additional medication, consider mechanisms for community drug distribution. If consultations are required, consider using telecommunication to contact patients or study participants.

Managing Vulnerable Populations

- It is clear from recent evidence that elderly populations, immunocompromised individuals or those who have other comorbidities are at higher risk of developing severe pneumonia and dying from the disease. While HIV- or TB-infected individuals have not been studied closely yet regarding their susceptibility to COVID-19, it is assumed that these individuals are more vulnerable to the virus and should take extra precaution.
- PEPFAR-funded programs should work with host governments, including ministries of health and other stakeholders, to develop plans that maintain support to individuals on antiretroviral therapy (ART) while minimizing their risk of exposure to COVID-19. Exposure of both clients and staff to health care facilities caring for patients with COVID-19 should be minimized wherever possible. Multi-month dispensing, flexible service delivery models, and mobile communication (all prioritized approaches for client-centered services) may increase continuity of ART and decrease the need for health facility visits. Contingency planning is critical to ensure the supply

chain and human resources for health are well equipped to avoid severe disruption to service continuity.[5]

Advancing Health Worldwide

Lastly, our mission of *advancing health worldwide* includes serving the local communities of Northern California as well as populations abroad. We appreciate the efforts that UCSF faculty and staff are making to support international communities and partners in response to the COVID-19 pandemic.

Resources

UCSF Resources
- [UCSF COVID-19 Resource Page](#)
- [UCSF COVID-19 Guidance for Researchers](#)
- [UCSF IRB COVID-19 Resources](#)

World Health Organization Resources
- [WHO COVID-19 Technical Guidance](#)

US Government Resources
- Consult the [CDC website](#) for the most up-to-date information.
- For the most recent information on what you can do to reduce your risk of contracting COVID-19, please see the [CDC's latest recommendations](#).
- Visit the [COVID-19 crisis page on travel.state.gov](#) for the latest information.
- US State Department – [Country-Specific Information on COVID-19](#)
- Visit the [Department of Homeland Security's website](#) on the latest travel restrictions to the U.S.

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[5] Secretary of State Mike Pompeo. Memo: PEPFAR Operations in Context of COVID-19. March 17, 2020.