

THE AGA KHAN UNIVERSITY
OFFICE OF RESEARCH AND GRADUATE STUDIES

COVID-19: Standard Operating Procedures (SOPs) for Research

As the COVID-19 pandemic evolves, the AKU Office of Research and Graduate Studies (ORGS) under the guidance of AKU Executive Committee has developed standard operating procedures (SOPs) to continue research projects during COVID-19 pandemic. In doing so international best practices have been studied and academic expert groups on research administration duly consulted.

AKU researchers may initiate, reinstate or continue to conduct research operations if guidelines for reducing risk and exposure to COVID-19 are followed and do not conflict with country and international (CDC, WHO, etc.) regulations.

Please note that this is a living document and flexible to amendments based on changing situation of COVID pandemic in each country where AKU operates.

A detailed policy on disruption to research is also being formulated.

1.0. ESSENTIAL RESEARCH ACTIVITIES:

Please note that in case of complete or partial city lockdown imposed by local or national government authorities during COVID-19 pandemic, only studies classified as “Essential Research” will be permissible.

Essential Research can be carried out with due biosafety considerations for AKU researchers and the study subjects.

Essential research activities include:

1.1. COVID-19 RELATED RESEARCH

- Studies that have a timeline for deployment that could address the current pandemic.
- Involve new clinical trials and other new research essential to the health and/or well-being of patients, healthcare workers, first responders or the general public.

1.2. NON COVID-19 STUDIES (ongoing or new)

- Are necessary for completion of a time bound deliverable
- Would pose a safety hazard to human subjects, if discontinued
- Maintain critical equipment in facilities and field-based laboratories

- Collect /maintain critical biological samples and living organisms
- Involve clinical trials and other research essential to the participant/study subjects as determined by the PI of the study and donor agency
- Have government mandated security and access approvals to initiate/continue during this time
- Cannot be performed remotely, and whose activity is deemed critical
- That if not initiated/ discontinued would generate significant data and sample loss - including laboratory or field work
- Are longitudinal or seasonal and discontinuation or non- initiation would result in loss of significant data or samples

Researchers may have additional research activities that can be considered as essential, as well as variations to above descriptions appropriate to specific research activities and locations. For any such additions or variations researchers must consult their respective Associate Dean for Research or Entity Research Leads or Entity Heads (as appropriate) to seek guidance.

2.0. GUIDELINES FOR LAB, ANIMAL & CLINICAL RESEARCH:

Following guidelines are for researchers who desire to initiate/reinstate/continue lab, animal and clinical research (including clinical trials) at AKU during COVID-19 pandemic irrespective of lockdown status:

- CMO/Hospital CEO approval will have to be obtained to conduct face-to-face data collection from any AKUH facility (including secondary hospitals) during COVID-19.
- Studies involving laboratory work (on-campus/off-campus) shall consult Institutional Biosafety Committee (as applicable) before starting/resuming lab work. For detailed guidelines please refer to Annexure 1.
- Ethics Committee for Animal Care and Use (ECACU) will advise on resumption/initiation of animal research studies. For detailed guidelines please refer to Annexure 1.
- PIs should work with Purchasing and Supply Chain Management (PSCM) and external suppliers to ensure timely availability of reagents/supplies to continue lab procedures without any interruption.
- The PI should provide appropriate masks, sanitizers, and/or other applicable PPE to be used by the project staff while working in any facility or during any face-to-face interaction with study participants.
- Staff should always maintain spatial separation to ensure social distancing.

3.0. GUIDELINES FOR OFF-CAMPUS FIELD RESEARCH:

For field research activities during COVID-19 pandemic (irrespective of lockdown status), AKU research staff must comply with the following guidelines:

- Permissions from all applicable government regulatory bodies must be in place before initiating any travel to field sites.
- Personal protective equipment (PPE): The PI should provide appropriate masks, sanitizers, and/or other applicable PPE to the field staff. The type of appropriate PPE will depend on nature of project activities, local and national guidelines, and on the type of interaction with study subjects
- Before departure, each person going to the field (including drivers) should be screened for COVID-19 symptoms and an Employee Medical Screening checklist should be completed as prescribed by each AKU entity (*Reference 9).
- Before departure, the field staff/supervisor should prepare and submit (wherever possible) their field plan to the PI/designee and AKU's Safety and Security must be informed about the plan.
- General disinfection guidelines: Use disinfectant wipes on surfaces that are touched or used by multiple people, e.g. data collection equipment, field vehicles, etc. As a substitute, a spray bottle with disinfectant solution can also be used. Shared items must be disinfected before and after every use.
- At all times maintain spatial separation. limit researcher density and enforce staff members to wear appropriate masks. The number of persons in each vehicle should be limited as per country specific government directives (as applicable).
- Field research activities should not be initiated and be suspended in localities that have COVID-19 positive cases and/or have been sealed by any government agencies. Planned routes of travel to and from field locations should be developed to either circumvent such areas or minimize encounters with the general public and local authorities while transiting through.
- For overnight trips, every possible effort should be made to provide individual accommodation arrangements for each field staff.
- If any person visiting field or planning to visit field shows COVID-19 symptoms, he/she should immediately report it to PI of the study.
- A written undertaking should be signed by all AKU employees undertaking field research to assure that they understand all the potential risks of contracting COVID-19 and their institutional medical coverage in case of illness. Please refer to AKU Research Office for the desired template.

4.0. PROCESS TO INITIATE/RESTART/CONTINUE RESEARCH ACTIVITIES:

Researchers desiring to initiate/reinstate/continue research activities during COVID-19 pandemic must submit a request form "[Request to initiate/reinstate/continue research during COVID-19](#)" (attached as Annexure 2) in consultation with department chair for approval of Entity Head/ Associate Dean Research/ Entity Research Lead (as applicable).

It is the responsibility of the PI and Entity Head to ensure that PPE are in place during the conduct of research either from currently active grant (preferred option) or entity budget (as feasible). All new grants being approved should factor in PPE in their budgets.

Principal Investigator's signature on form would verify;

- thorough review of COVID-19: Standard Operating Procedures (SOPs) for continuation of research during COVID-19 pandemic.
- thorough review and validity of form content.
- obtained consent from department chair to initiate/reinstate/continue his/her research work.
- compliance with any entity specific Employee Safety Checklist.
- written undertaking from all AKU employees involved in field activities has been obtained as specified in the SOPs

The request form after Entity Head/Associate Dean's/Entity Research Lead's recommendations and signatures must be submitted to Office of Research and Graduate Studies (ORGS).

5.0. Reference:

1. One AKU Coronavirus Updates <https://one.aku.edu/covid-19/Pages/coronavirus-live-updates.aspx>
2. CDC Guidelines on Disinfection: <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cleaning-disinfection.html>
3. CDC Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators: <https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html>
4. WHO - Laboratory biosafety guidance related to the novel coronavirus (2019-nCoV): https://www.who.int/docs/default-source/coronaviruse/laboratory-biosafety-novel-coronavirus-version-1-1.pdf?sfvrsn=912a9847_2
5. CDC Guidelines on Social Distancing. <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/social-distancing.html>
6. WHO COVID-19 Advice for Public: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public>
7. Mitigating Impacts to Research Activities Due to COVID-19 (University of Washington). <https://www.washington.edu/research/announcements/mitigating-impacts-to-research-activities-due-to-covid-19/>
8. Guidance on Essential Research (Texas A&M University). <https://vpr.tamu.edu/guidance-on-essential-research-4-2-2020>
9. *Sehat check app: <https://one.aku.edu/Apps/Announcements/Pages/Detail-Page.aspx?title=Employee-Health-and-Safety---Sehat-Check&itemID={76AE0F65-C6EC-4B72-987F-AC3CBFFF1C88}>

ANNEXURE 1

Guidelines for Conducting Lab and Animal Research during COVID-19 Pandemic (*will be uploaded on intranet*)

Following guidelines are provided by AKU Institutional Biosafety Committee (IBC) and Ethics Committee for Animal Care and Use (ECACU) to AKU employees involved in laboratory and animal research.

1.0. Social Distancing:

- COVID-19 is readily transmitted from person-to-person when they are in each other's breathing zones. It is imperative to maintain required social distancing in order to minimize the spread in case anyone is affected.
- To ensure social distancing, 1 person at a time should work on each bench space (approx. 120 square feet of space). No close group discussions are allowed. For any meeting or discussion, maintain distance of 6 feet or use emails. In case of official/team meetings, please use online forums such as Microsoft Teams.
- If the research space, you are working appears too small to meet above requirement, consider staggering work in shifts so essential requirement is achieved.
- Implement a work schedule so that individuals can avoid using the same space or equipment at the same time as other individuals.

2.0. Personal Protective Equipment:

Individuals working in labs must wear personal protective equipment, potentially more than they are typically included in their standard operating schedule.

2.1. Masks (Required):

- Workers should wear protective masks (surgical mask)
- The use of one mask per worker per day is recommended. If masks must be re-used due to shortages, ensure it is properly labeled and stored in clean dry area preferably in properly labeled paper bag.
- Mask must be changed if visibly soaked / damaged.

2.2. Gloves (Required)

- Plastic gloves (or other type of disposable gloves provided by your department) should be worn.
- Avoid touching your face (or mask) with your gloved hands.
- Wash and dry hands before putting fresh gloves on.
- Workers using hazardous materials, chemicals and biological agents must continue to follow their specific glove use practices.
- Replace torn gloves with a new pair.

- After removing gloves, wash and dry hands thoroughly. If you are not near handwashing facilities, disinfect your hands with hand sanitizer, then wash hands with soap and water as soon as you can.

2.3. Gown (conditionally required in animal laboratory)

- Impermeable gown is required for work on animals including
 - performing procedures
 - administering drugs by injection or orogastric tube
 - collecting blood, urine or feces
 - assessments requiring holding animal out of its cage
- Impermeable gown is NOT required for
 - lifting animal for general inspection
 - measuring body weight
 - shifting animal to another cage

3.0. Hand hygiene:

Personnel should sanitize their hands upon entering and leaving the laboratory. This can be done by hand washing for 20 seconds with soap and water, or use of a hand sanitizer.

4.0. Surface Disinfection:

- Recent research shows that COVID-19 can survive up to 72 hours (3 days) on plastic and stainless-steel surfaces. From the first moment of viral contamination, the amount of the live virus on surfaces decreases significantly over these time periods.
- It is critical that every high-touch surface in the work area (drawer and cupboard handles, faucet and dispenser handles, supply bottle tops, etc.) be frequently sanitized.
- Daily disinfection of work benches before and after use is a mandatory component of good laboratory practice and must be implemented in full spirit. disinfection schedule must be in place that should be posted in the lab and initialed upon completion on daily basis.

5.0. Prohibition advice against occupancy:

To ensure your and others safety in the lab, staff is strongly encouraged to disclose and stay at home if they

- have fever or respiratory symptoms, or have been in contact with anyone with these symptoms for the past 14 days;
- have tested positive for COVID-19 and have not yet been cleared to return to work by an authorized public health official; or infectious disease consultant.
- have within the last 14 days returned from an area with reported community spread of COVID-19.

ANNEXURE 2

The Aga Khan University Office of Research and Graduate Studies

Request Form to initiate/reinstate/continue research during COVID-19 Pandemic

1. Name of PI:	2. Designation:
3. Department:	4. Entity:
5. Email:	6. Contact #

7. Project Title:

--

8. Purpose of research/field work:

--

9. Activities involved in research/field work:

--

10. Does your study involve collection of biological samples (respiratory/urine/feces /environmental)? If yes, have you taken a fresh approval from Institutional Biosafety Committee (IBC) for risk assessment of such samples during COVID-19 pandemic?

--

11. Location of field work (if applicable and please specify if it includes over-night stay)

Place(s) of Visit	Duration (hours)	Frequency per week	No. of persons	No. of Vehicle

12. Duration of research/field work:

Start Date:		End Date:	
-------------	--	-----------	--

13. Why is it necessary to continue research/field work during COVID-19 pandemic? Explain briefly about time sensitivity or critical nature of the field research (200 words max)

--

14. What steps will be taken to mitigate risk of COVID-19 exposure? Describe your ability to comply with physical distancing and hygiene protocols as required by Public Health in the area where you are working during all aspects of the field research activities (200 words max)

--

15. Have you obtained necessary approvals (for off-campus research)? (please attach copies)

Approvals	Yes/No/NA	If No, state reason
a) District commissioner / Union Council		
b) Public/Private Hospital/Clinic administration (if applicable)		

16. Have you taken following AKU departments on board? (please attach copies)

Approvals	Yes/No/NA	If No, state reason
a) Safety and Security (for off-campus)		
b) Transport		
c) CTU (for clinical trials)		
d) ECACU (if applicable)		
e) Juma Lab (if applicable)		

17. What measures are planned to deal with COVID related emergencies?

--

Note: The signature of Principal Investigator verifies;

- thorough review of COVID-19: Standard Operating Procedures (SOPs) for continuation of research (attached)
- thorough review and validity of above content.
- obtained consent from department chair to initiate/reinstate/continue his/her research work.
- compliance with entity specific Employee Safety Checklist (See reference *9)
- written undertaking from all AKU employees involved in field activities has been obtained as specified in the SOPs

PI Signature:	Date:
---------------	-------

18. Entity Head/Associate Dean/Entity Research Lead recommendation:

Name and Sign:	Date: