

Human Research Protection Program Institutional Review Board (IRB)

Frequently Asked Questions (FAQs) for Faculty, Staff and Students during COVID-19 Pandemic

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For more information please contact irb@aub.edu.lb

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Section 1: General FAQs:

- Is the IRB functioning during the COVID-19 emergency?
 Yes, the IRB is functioning and has switched its operations to electronic communications.
- 2. How do I apply electronically?

For the time being, send your submission to irb@aub.edu.lb and cc Ms. Lina Onsi le08@aub.edu.lb for Social and Behavioral Sciences (SBS) research studies, or cc Ms. Abeer Dakik ad17@aub.edu.lb for Biomedical research studies. If unsure, you can email the IRB with a short query for guidance.

- 3. Do I need IRB approval before I can apply for research funding?

 No, but IRB must be secured before conducting any research activities.
- 4. Do I have to sign the IRB application form?

Yes, the Principal Investigator (PI) must sign it electronically, and attach an email statement from the chairperson of your department confirming approval of submission if he/she could not sign-off electronically.

- 5. Does the IRB need a hard copy of my application?

 There is no need for hard copies. The IRB is operating electronically until further notice.
- 6. What can I do to avoid delays?

For initial submission, submit all the required documents: an IRB application form, your research proposal, consent forms (Arabic and English for studies involving any subject for whom Arabic is the primary language), and data collection tools, etc.

Submit an "EXEMPT" form for studies that meet the eligibility criteria (listed on the form). Submit an "EXPEDITED" form for all other applications. SBS and Biomedical application forms and templates are available at:

https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx

Check that your consent document includes all the required elements. You can refer to the informed consent form checklist available at:

https://www.aub.edu.lb/irb/Documents/1-1%20Informed%20Consent%20Form%20Checklist.pdf

7. How do I respond to reviewer's comments?

For response and rebuttals to the IRB, provide a point-by-point response to the IRB queries and modify all the documents accordingly (submit both tracked and clean copies). Cut and paste all the changes you have made into your rebuttal letter to make it quicker for the reviewer to approve your changes.

8. Can I conduct research at AUBMC or involving AUBMC patients if I am not a clinician?

Yes, you can but only in collaboration with an AUBMC clinician with active clinical privileges as a an AUBMC medical staff member. Currently due to the COVID-19 crisis and until further notice, only online or remote data collection is permitted.

9. Can I collect data overseas?

Only if you can collect the data online/remotely. If you are an international student in an overseas country now, you can contact Ms. Nour Bekhaazi for advice nb85@aub.edu.lb, cc irb@aub.edu.lb

10. Can I collaborate with an overseas investigator?

If AUB is the lead site for the study, you can identify your collaborator as a co-investigator on the IRB application form. If your collaborator's institution is the lead site for the study, apply for AUB IRB approval with you as the Principal Investigator in Lebanon. The research documents, especially the consent document, must comply with AUB/AUBMC and IRB requirements. Submit a copy of the IRB approval from the overseas site with your application. Until the COVID-19 crisis is over, only studies that conducted online/remotely may be approved.

11. Can I be Principal Investigator for a student at another university?

Yes, you can but until further notice, the study should be conducted online/remotely. Apply for AUB IRB approval with you as the Principal Investigator at AUB. The research documents, especially the consent documents, must comply with AUB/AUBMC and IRB requirements. Submit a copy of the IRB approval from the overseas site with your application. Until the COVID-19 crisis is over, only studies that can be conducted online/remotely may be approved.

12. What happens if I conduct a research study without IRB approval?

Please do not start any research activities prior to securing IRB approval because this is considered major non-compliance by AUB/AUBMC regulations and policies. Conducting studies without prior IRB approval could result in suspension of your research privileges, halting of funding for a project, retraction of manuscripts, and/or reporting to funding agencies.

13. Does my study need a Non-Disclosure Agreement (NDA)?

You may contact the Office of Grants and Contracts (OGC) when you are collaborating with other institutions. The IRB Office will help you if you need additional assistance.

14. Can the IRB process urgent applications?

The IRB has limited capacity to process urgent applications other than those related to the COVID-19 crisis and those for students' research studies. Every effort will be made to expedite processing of all submitted applications.

15. Can I call or come to the IRB Office?

Until further notice, please do not call or visit the IRB Office. You can send all queries to irb@aub.edu.lb.

Section 2: Social and Behavioral Sciences (SBS) IRB targeted FAQs

- 16. How does the COVID-19 emergency affect existing research studies?
 - Submit a continuing review form for studies conducted entirely online/remotely before the renewal due date. Apply for a modification to your approved study via email to conduct your study on online/remotely. An email message to the SBS IRB staff is all you need to secure approval for changing to online/remote recruitment, consent, and data collection. If you cannot conduct your study online/remotely, you need to put it on hold until the COVID-19 crisis is over and you receive IRB approval to resume.
- 17. How does the COVID-19 crisis affect students' research studies?

 Applications for studies that can be conducted online/remotely are by

Applications for studies that can be conducted online/remotely are being processed and have top priority. The IRB has approached several students via WebEx meetings to help them modify their recruitment, consenting and data collection procedures. If your study cannot be conducted online/remotely, you need to contact your advisor and then notify the IRB how you would like to proceed.

- 18. How does the IRB prioritize approval of amendments during the COVID-19 crisis? Amendments that involve online/ remote data collection are prioritized over changes that cannot be implemented until the COVID-19 crisis is over.
- 19. How does the COVID-19 emergency affect new research studies?

Your study may be approved if it does not involve face-to-face interaction with research participants. Consider using the technology recommended by IT for teaching and working from home. If you cannot conduct your study online/remotely, you can apply for approval but will not be able to start your study until the COVID-19 emergency is over and you receive IRB approval to resume. The IRB is prioritizing approval of studies about the COVID-19 crisis over other applications.

- 20. What if my application needs a full-board review?
 - The IRB board meetings are being conducted electronically. Your application will be processed as usual.
- 21. Can I conduct research involving AUB/AUBMC faculty/staff as participants during the COVID-19 crisis?

Yes, but only if your study can be entirely conducted online/remotely. (Updated statement can be found at:

 $\frac{https://www.aub.edu.lb/irb/Documents/IRB\%20COVID19\%20study\%20conduct\%20memo\%20}{Apr\%202\%202020.pdf}$

- 22. Can I conduct research on students/medical students during the COVID-19 crisis? Yes, but only if your study can be entirely conducted online/remotely.
- 23. How do I get email lists for my studies?

For studies targeting faculty and staff members at AUB/AUBMC, the IRB Office will secure the email addresses for you as usual. AUB policy prevents mass email messaging so you need to specify and justify the number of email addresses you need. Submit the request for students' email addresses form for studies involving students as research participants https://www.aub.edu.lb/irb/Documents/6-11.pdf

24. What if I get a low response rate?

The IRB approves up to three reminder messages for online/remote surveys. If the response rate is still poor, submit an amendment for IRB review and approval. Your options include: 1. Request more email addresses, 2. Increase the number of reminder messages, 3. Post your flyer/invitation on social platforms after securing administrative approvals, or 4. Propose any other online/remote research strategy.

25. Who can faculty members contact for help?

- For SBS research studies being conducted by researchers from Faculty of Medicine (FM), Hariri School of Nursing (HSON), Faculty of Health Sciences (FHS) and Olayan School of Business (OSB), you can contact Ms. Nadine Kamal nk93@aub.edu.lb and cc Ms. Lina Onsi le08@aub.edu.lb.
- For SBS research studies being conducted by researchers from Faculty of Engineering (FEA), Faculty of Arts and Sciences (FAS) and Faculty of Agriculture and Food Science (FAFS), you can contact Ms. Zahraa Sadek zs56@aub.edu.lb and cc Ms. Lina Onsi le08@aub.edu.lb.
- Faculty members who have questions about student projects can contact Ms. Nour Bekhaazi nb85@aub.edu.lb and cc Ms. Lina Onsi le08@aub.edu.lb.

26. Who can students contact for help?

IRB has a student help service. You can contact Ms. Nour Bekhaazi nb85@aub.edu.lb and cc Ms. Lina Onsi le08@aub.edu.lb. Ms. Bekhaazi is available for WebEx meetings. Ask your advisor to attend if possible.

27. Will the SBS IRB Board meet?

Yes, SBS board meetings will be conducted via WebEx on regular basis.

28. Can I be the Principal Investigator for a student at another university?

Yes, you can but until further notice, the study should be conducted remotely/online.

Section 3: Biomedical IRB targeted FAQs

29. Who can I contact if I need help?

For Biomedical research studies, you can contact Ms. Karine Ismail <u>ki09@aub.edu.lb</u> or Ms. Dana Fakhreddine df17@aub.edu.lb and cc Ms. Abeer Dakik ad17@aub.edu.lb.

30. How can I recruit research subjects during the COVID crisis?

Currently, the Biomedical IRB is approving recruitment methodologies that do not require person-to-person contact. (Updated statement can be found at: https://www.aub.edu.lb/irb/Documents/IRB%20COVID19%20study%20conduct%20memo%20Apr%202%202020.pdf

- 31. How are current submissions being processed by the Biomedical IRB?

 For newly submitted Biomedical research studies, currently the IRB is prioritizing COVID-19 studies and research studies that can be conducted online/remotely with no person-to-person interaction.
- 32. How does the IRB process renewals and continuing reviews for studies with potential therapeutic benefit (examples: most interventional studies with drugs, devices, procedures, behavioral interventions)?

 The Biomedical IRB is renewing therapeutic studies to continue research related interventions. For already recruited participants, the IRB is requesting from Principal Investigators to weight the research related intervention and the research related intervention and the research research representation and the research related intervention and the research research representation and the research research representation and the research related intervention and the research research representation and the research research research research research research related interventions.

For already recruited participants, the IRB is requesting from Principal Investigators to weigh the risks of person-to-person contact against the potential benefits of the study intervention and monitoring. Researchers are asked to pause on enrolling new research participants that require person-to-person contact unless there is a compelling reason that is communicated to the IRB prior to initiating this enrollment.

33. How does the IRB process renewals and continuing reviews for studies with no potential therapeutic benefit (examples: observational studies, epidemiological studies and studies collecting non-time sensitive biospecimens)?

The Biomedical IRB is releasing renewals on time. However, researchers are asked not to enroll new participants in studies requiring person-to-person contact nor continue to conduct face-to-face visits. Researchers are asked to consider changing data collection from face to face interaction to telephone or online modalities.

34. How are amendments being processed?

Amendments made in consideration of the COVID-19 pandemic are prioritized. Others are being processed but researchers are asked to follow the recommended guidelines during the COVID-19 crisis. Please refer to this link for more information:

 $\frac{https://www.aub.edu.lb/irb/Documents/IRB\%20COVID19\%20study\%20conduct\%20memo\%20}{Apr\%202\%202020.pdf}.$

35. Can the Biomedical IRB process urgent applications?

Currently the IRB is prioritizing COVID-19 research studies and trying to approve them the fastest way possible:

- For Biomedical research studies submitted to the IRB prior to the COVID-19 crisis, researchers are encouraged to modify the recruitment strategy by applying safeguards to minimize risks during the crisis.
- For Biomedical research studies that are approvable but unmodifiable, the IRB is releasing the approval letter but requesting from researchers to adhere to the recommended guidelines and not to initiate recruitment during the COVID-19 crisis.
- The IRB also approached several researchers and conducted WebEx meetings to help them modify their recruitment and consenting procedures to be able to collect data during the current crisis.

36. What if my application needs full-board review?

The Biomedical board is meeting remotely almost every two weeks. Your application will be processed as usual.