

Q&A for Principal Investigators

Clinical Research Institute American University of Beirut Medical Center

The following document was developed to guide PIs and answer their questions that are related to clinical trials. The document answers questions relevant to several departments that are involved in this process.

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Clinical Research Institute

1. How to learn more about the Clinical Research Institute research support and services?

The Clinical Research Institute (CRI) provides clinical investigators with research support and infrastructure, as well as education and training. To learn about the CRI units and services, please visit the CRI [website](#).

2. Who do I contact if I need assistance with planning or conducting statistical analyses?

For statistical analysis, please contact Dr. Hani Tamim, director of the Biostatistics Unit (BSU) at the CRI for help by emailing him at htamim@aub.edu.lb or Ms. Aurélie Mailhac, the BSU Analyst, at am138@aub.edu.lb. For more information, please visit the BSU [website](#).

3. Who do I contact if I need assistance in planning, designing, and conducting systematic reviews and meta-analyses in the clinical and public health fields?

For any inquiries regarding the methodology of clinical trials and systematic reviews, please contact Dr. Elie Akl, director of the CRI and director of the Clinical Epidemiology Unit (CEU) for help at ea32@aub.edu.lb or Ms. Lara Kahale at lk45@aub.edu.lb. For more information, please visit the CEU [website](#).

4. Who do I contact to provide support regarding applying the GRADE methodology to produce systematic reviews and guidelines?

For any inquiries regarding the use of the GRADE methodology, please contact Dr. Andrea Darzi, the assistant director of AUB Grade center at ad55@aub.edu.lb or visit the AUB Grade center [website](#).

5. Are there any facilities available that I can use to conduct my clinical study?

The Clinical Research Unit (CRU) at the CRI provides space for patient encounter and physical assessment as well as nursing services for study related tasks. To book the CRU, you are kindly requested to fill-in the CRU use application form available [here](#) and send it along with needed documents (detailed in the form) to Ms. Lara Al-Hakim la51@aub.edu.lb. For more information, please visit the CRU [website](#).

6. Are there any educational programs, trainings, and workshops for AUB faculty and staff members who are interested in medical research?

The Research Education Unit (REU) at the CRI offers a number of educational programs and a wide range of training workshops to individuals inside and outside AUB. For further inquiries, please contact Dr. Mona Nabulsi, director of the REU, at mn04@aub.edu.lb or the coordinator Ms. Sara Khansa at sk77@aub.edu.lb. For more information, please visit the REU [website](#). Please visit this [webpage](#) to check all upcoming REU events.

7. Where can I locate possible collaborators for clinical trials?

A database of research faculty and their interests is available at the following [link](#) or you can visit the Medical Research Volunteer Program (MRVP) [website](#), or the Fellowship and Residency Research Program (FRRP) [website](#).

Institutional Review Board (IRB) and Human Research Protection Program (HRPP)

1. How can I learn more about the IRB?

All information related to [IRB](#) policies and procedures, application process and forms are available at this following [link](#).

2. How to get the Collaborative Institutional Training Initiative (CITI) certification?

The HRPP at AUB requires certification of the Principal Investigator (PI) and all research team members involved in the conduct of research with human subjects. For more details please visit this [page](#). CITI certificate is required prior to starting any research-related activity and it should be submitted to the IRB prior for approval of new, renewal, and continuation applications, or for amendment applications. The principal investigator is responsible for assuring that all personnel listed on the protocol have completed the CITI training requirements. The CITI certificate needs to be renewed every three years.

3. What is the AUB policy on certification and re-certification?

To check the policy, please visit this [website](#).

4. When is CITI certification not required?

CITI certification is not required from investigators or research personnel not involved in human subject research, identifiable human samples, or records. You can contact the IRB office for any inquiries on whether your study requires CITI certification or not at irb@aub.edu.lb.

5. How do I contact regarding trial insurance, professional liability, general liability and all other research related insurance coverage?

Please contact Ms. Abeer Dakik, Senior IRB Regulatory Analyst, at ad17@aub.edu.lb or by phone (extension number 5442).

6. Who should complete Good Clinical Practice (GCP) course?

GCP is required for all investigators who hold Investigational New Drug (IND) or Investigational Device Exemption (IDE). GCP is strongly recommended for investigators and research staff participating in FDA-regulated research involving a drug, device or biologic that may undergo an FDA audit. For further inquiries, please contact the IRB administrators at extensions 5442 or 5443, or send an e-mail to irb@aub.edu.lb.

7. How can I access IRB application forms that need to be submitted?

IRB Biomedical and Social and Behavioral studies applications forms are available on this [website](#).

Office of Grants and Contracts (OGC)

1. What is the mission of the OGC?

To learn more about the OGC mission and services, please visit this [website](#).

2. What are the different functions of the OGC?

OGC has three different functions available on this [website](#).

3. What are the funding information and resources available at AUB?

Research at AUB is supported by various national, regional and international philanthropic organizations, governmental institutions and non-governmental institutions, foundations, as well as private companies. The lists of some of the funding agencies which have previously or are currently funding research at AUB are available on this [website](#).

4. What are the different policies and procedures for sponsored research?

All sponsored research policies and procedures are available on this [website](#).

5. What is the process of developing a proposal?

All information related to proposal development and review processes are detailed on this [website](#).

6. What is the information related to grant administration?

All information related to grant administration is available on this [website](#).

7. Who is the contact person regarding transferring a grant to AUB or requesting a statement declaring to whom funds should be paid?

It would be best to email Mr. Makram Halawani, Federal Grants and OGA Manager at the OGC, at mh149@aub.edu.lb or contact him by phone (extension number 2977).

8. What is the budget preparation process?

The OGC offers some advice when preparing the budget that could be useful to you. Please click [here](#) for further details. To create a budget for clinical trials it is advisable to have a process and coordinate with your departmental administrator. Please click [here](#) for further details and/or contact Ms. Vicky Nassar at vn01@aub.edu.lb or contact her by phone (extension number 7420).

9. What are the eligibility criteria and responsibilities of principal investigators for applying to an external funding?

Information regarding principal investigators eligibility and their responsibilities for applying to an external funding are available on this [website](#).

- 10. Where can I get AUB institutional profile information as well as its tax ID number?**
The tax ID number of the institution is 13-5596846. AUB institutional profile is detailed on this [website](#).

Medical Research at AUB Faculty of Medicine (FM)

- 1. Where can I learn more about the medical research at AUB faculty of medicine?**
All information related to the medical research at AUB FM is available on this [website](#).
- 2. Where can I learn more on the clinical and translational research?**
For more information regarding the clinical and translational research, please visit this [website](#).
- 3. Are there any guidelines for developing clinical databases and datasets for research purposes?**
The guidelines are available on the research [website](#).
- 4. Which entities govern data collection for database or clinical dataset?**
 - Clinical database is governed by Medical Records.
 - Quality improvement (QI)/quality assurance (QA) registry are governed by the hospital director or designee.
 - Research registry is governed by the IRB.
 - Government mandated registry is governed by Ministry of Health (MOH).If you have any questions, please contact the IRB (ext. 5445) or check this [document](#).
- 5. What are the guidelines and procedures to apply for the Medical Practice Plan (MPP) grant?**
Researchers at the Faculty of medicine benefit from an intramural funding opportunity sponsored by the Medical Practice Plan (MPP). Details are available on this [website](#).
- 6. How to learn more about the University Research Board (URB) and what are its research funding guidelines?**
To learn more about the University Research Board ([URB](#)) and its funding guidelines please visit this [website](#).
- 7. Where can I find out more about extramural funding agencies?**
Faculty members are encouraged to seek extramural funding from local, regional, and international agencies listed on this [website](#).
- 8. Are there any special rates for research related laboratory and other services at AUBMC?**

There are research rates that are offered by AUBMC. For any requests you need to fill in the use of hospital equipment form available [here](#). As for the blood tests, it is advisable to contact department of pathology and laboratory medicine (ext. 5202), listing the blood tests you want to run and inquiring about research rates.

9. Who is the contact person for all questions relevant to drug supply in clinical trials and their requirements?

Please contact Dr. Ulfat Usta, director of the pharmacy department, at uu00@aub.edu.lb or by phone (extension number 6574).