­

REQUEST FOR APPROVAL OF MEDICAL RECORD REVIEW

|  |
| --- |
| **Questions to determine if the study qualifies for retrospective medical record review:**1. Will the medical information to be accessed be limited to ONLY records of the deceased?

[ ]  Yes [ ]  No **If you answered “Yes”, stop filling this form as proposed work may not constitute Human Subject Research. You may contact the IRB for help with determination.**1. Will the information collected be used to create a data archive for future research?

[ ]  Yes [ ]  No **If you answered “Yes”, stop filling this form and complete a full IRB application form including the protocol, informed consent forms, and all supporting documents.**1. Are there plans to contact subjects for follow-up or to collect any information using assessment tools or other means to complete the information that is not currently available in the records?

[ ]  Yes [ ]  No **If you answered “Yes”, stop filling this form and complete a full IRB application form, including the protocol, informed consent forms, and all supporting documents.**If you answered “No” to all the above questions, please proceed with filling this form.  |

**INSTRUCTIONS**

This form can be used to apply for studies that qualify under retrospective chart review. This form is not for applying for Full Committee Review or prospective studies that fall under Expedited Review.

**How to complete your application and begin the IRB review process:**

1. This form **must not be** handwritten.
2. Fill out **all the sections** on this form completely.
3. The form must be filled without any deletions or alterations to the pre-printed content; otherwise, this will disqualify the submission and the application will not be processed.
4. Please refer to Appendix I at the end of the form to guide you while filling the application.

**CONTENTS OF APPLICATION FORM**

|  |
| --- |
| [1. PROJECT IDENTIFICATION 5](#_Toc142473088)[2. FUNDING 7](#_Toc142473089)[3. ABSTRACT 7](#_Toc142473090)[4. DESCRIPTION OF RECORDS 8](#_Toc142473091)[5. PROCESS OF RECORDS REVIEW 8](#_Toc142473092)[6. WAIVER OF INFORMED CONSENT 10](#_Toc142473093)[7. PERSONAL/FINANCIAL INTEREST 11](#_Toc142473095)[8. BIBLIOGRAPHY AND REFERENCES 11](#_Toc142473096)[Appendix I 14](#_Toc142473097) |

**DATE OF SUBMISSION TO INSTITUTIONAL REVIEW BOARD:**

**EXPECTED STARTING DATE OF STUDY:**

# PROJECT IDENTIFICATION

**1.1 Project Title**

(Project title on application must match title added to **all** corresponding documents.)

Click or tap here to enter text.

* 1. **Is this a student or FRRP Project?**

[ ] Yes [ ] No

|  |
| --- |
| 1.3 Principal Investigator: |
| **Name:** | **Department:** |
| **Phone number:** | **Email:** | **Faculty:** |
| **CITI certification:** ☐ Yes ☐ No ☐ Pending  | **Course module:**  | **Expiry date:** |
| **Position:** | [ ] Professor [ ] Associate Professor [ ] Assistant Professor [ ] Instructor [ ] Other If other, please indicate the position:Click or tap here to enter text. |

|  |
| --- |
| 1.4 Co-investigator/Staff: (Copy and paste table if necessary.) |
| **Name:** | **Department:** |
| **Phone number:** | **Email:** | **Faculty:** |
| **CITI certification:**☐ Yes ☐ No ☐ Pending | **Course module:**  | **Expiry date:** |
| **Position:** | [ ] Professor [ ] Associate Professor [ ] Assistant Professor [ ] Instructor [ ] Research Assistant [ ] Research fellow [ ] Other If other, please indicate the position:Click or tap here to enter text. |

|  |
| --- |
| 1.5 Study Coordinator: (Copy and paste table if necessary) |
| **Name:** | **Department:** |
| **Phone number:** | **Email:** | **Faculty:** |
| **CITI certification:**☐ Yes ☐ No ☐ Pending | **Course module:**  | **Expiry date:** |
| **Position:** | [ ] Professor [ ] Associate Professor [ ] Assistant Professor [ ] Instructor [ ] Research Assistant [ ] Research fellow [ ] Other If other, please indicate the position:Click or tap here to enter text. |

|  |
| --- |
| 1.6 Key study personnel (s): Include all people responsible for the design and conduct of the study (if collaborators at other institutions, go to “1.7”). |
| **Name:** | **Department:** |
| **Phone number:** | **Email:** | **Faculty:** |
| **CITI certification:** ☐ Yes ☐ No ☐ Pending  | **Course module:**  | **Expiry date:** |

|  |
| --- |
| 1.7 Collaborators: Collaborators at other institutions outside AUB/AUBMC: |
| **Name:** | **Department or Affiliation:** |
| **Phone number:** | **Email:** | **Faculty:** |
| **CITI certification:** ☐ Yes ☐ No ☐ Pending  | **Course module:**  | **Expiry date:** |
| **Position:** | [ ] Professor [ ] Associate Professor [ ] Assistant Professor [ ] Instructor [ ] Other If other, please indicate the position:Click or tap here to enter text. |

# FUNDING

* 1. **Is this research funded?**

 ☐Yes. Fill the below table and copy the same table for more than one source of funding, if applicable.

|  |  |
| --- | --- |
| Source of funding/Sponsor name |  |
| Status  | [ ] Funded [ ] Pending |
| Proposed annual budget |  |
| Role of funding agency  |  |
| Federal money (for example: NIH) | [ ] Yes [ ] No |

 [ ] No, explain how costs of research will be covered, if any:

 Click or tap here to enter text.

# ABSTRACT

**Provide a brief description (limited to 250 words), including:**

 *Refer to Note 1 under Appendix I*

* Aim/Hypothesis
* Background and significance
* Research design and methods
* Possible risks and benefits

Click or tap here to enter text.

# DESCRIPTION OF RECORDS

* 1. **Provide the number of charts to be reviewed.**

Click or tap here to enter text.

* 1. **Specify the inclusion/exclusion criteria.**

Click or tap here to enter text.

* 1. **Indicate the timeframe for record review.**

 *Refer to Note 2 under Appendix*

Records **from:** Click or tap to enter a date.**To:** Click or tap to enter a date.

Please note that retrospective review projects are limited to utilizing existing data available as of the date of IRB submission. Any information entered in or any records added to the research dataset after the submission date cannot be included in the scope of this retrospective review research activity. **Engaging in such actions is deemed a significant violation of both IRB and AUB policies and regulations.**

# PROCESS OF RECORD REVIEW

* 1. **Specify the source of information to be collected (for example: paper medical charts, electronic health records, pathology slides, diagnostic radiology material, etc.)**

|  |  |
| --- | --- |
| [ ] Electronic medical records  | [ ] Paper medical records |
| [ ] Pathology records  | [ ] Radiology records  |
| [ ] Approved quality insurance datasets | [ ] Other, specify:Click or tap here to enter text. |

* 1. **Specify the governing entity for the data source being accessed.**

|  |  |
| --- | --- |
| [ ] Medical Records Department  | [ ] Approved quality insurance datasets |
| [ ] Other, specify:Click or tap here to enter text. |  |

*Any database that is not governed by the Medical Records Department or approved as a quality improvement/quality assurance is not eligible for this submission.*

* 1. **Include a copy of the data collection tool, listing all variables to be extracted.**

**Only items listed on the tool may be extracted by the PI or authorized research personnel. Note that only the minimum information necessary to conduct the research should be extracted. After initial approval and before you can add any more variables, an amendment needs to be submitted and approved by the IRB.**

*Refer to Note 3 under Appendix I*

 [ ] Attached

* 1. **Identify how data will be collected and recorded and state the plans for maintaining confidentiality and security of the data.**

*Refer to Note 4 and 5 under Appendix I*

Click or tap here to enter text.

* 1. **Indicate who will have access to the data, and how access to the data storage (whether paper-based or electronic) will be monitored.**

*Refer to Note 6 under Appendix I*

Click or tap here to enter text.

* 1. **Does the PI or any other member of the research team have a direct existing clinical care relationship with the subjects whose records will be reviewed?**

[ ] Yes, all subjects.

[ ] Yes, some of the subjects.

[ ] No

If yes, describe the nature of this relationship.

 Click or tap here to enter text.

* 1. **Will information be collected from sources outside AUBMC (for example: UHS, private clinics of physicians affiliated to AUB/AUBMC, etc.)?**

[ ] Yes

[ ] No

If yes, please indicate name and location.

 Click or tap here to enter text.

**5.8 Will information be collected from outside sites or countries?**

[ ] Yes

[ ] No

If yes, please indicate name and location.

 Click or tap here to enter text.

***\*Note: This will require the submission of additional documents such as IRB/administrative approval from outside sites and ethical training of collaborators.***

**5.9 Will information be shared with outside entities?**

 [ ] Yes

 [ ] No

If yes, please indicate name and location:

 Click or tap here to enter text.

**If data sharing applies, please refer to the Office of Grants and Contracts for assistance in preparing the appropriate agreement.**

**5.10 How long will the data and/or identifiers be retained?**

 Click or tap here to enter text.

**5.11 How will the data and/or identifiers be destroyed when no longer needed for research purposes? If you are interested in de-identifying the data for good, please complete the Request to create a de-identified dataset form.** <https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx>

*Refer to Note 5 and 7 under Appendix I*

 Click or tap here to enter text.

# WAIVER OF INFORMED CONSENT

# Does the research pose greater than minimal risk to subjects?

[ ] Yes

[ ] No

**Please elaborate.**

 Click or tap here to enter text.

* 1. **Will the waiver adversely affect subject’s rights and/or welfare?**

[ ] Yes

[ ] No

Please elaborate.

Click or tap here to enter text.

* 1. **Describe why it would be impracticable to obtain the subject’s consent and authorization for use or disclosure without the waiver.**

*Refer to Note 8 under Appendix I*

Click or tap here to enter text.

* 1. **Are there any plans to provide subjects with additional pertinent information after their records have been reviewed?**

[ ] Yes

[ ] No

**If yes, please explain**.

Click or tap here to enter text.

# CONFLICT OF INTEREST

* 1. **Disclose any personal or financial interests in the research and as well as any relationship with the sponsor of the study, if applicable.**

Click or tap here to enter text.

# BIBLIOGRAPHY AND REFERENCES

* 1. **List up to five relevant publications that, in your opinion, would be helpful to the IRB in reviewing the study.**

Click or tap here to enter text.

**Principal investigator’s assurance statement:**

I agree to abide by the policies and procedures of the AUB IRB regarding the protection of human subjects including, but not limited to the following:

|  |
| --- |
| I certify that the information provided in this application is complete and accurate. |[ ]
| I understand that as principal investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights, safety and welfare of the human participants/subjects, and strict adherence to the study protocol and any conditions or modifications stipulated by the AUB Institutional Review Board.  |[ ]
| I will submit modifications of the protocol and/or any other documents to the IRB for approval prior to applying those changes in the study.  |[ ]
| Ensuring that all personnel involved in the study have completed the human subjects training online course offered by CITI. If the first language of personnel is other than what is available for training on CITI website, it is the PI’s responsibility to provide the personnel with efficient training. |[ ]
| Ensuring that the study will be conducted by qualified personnel who are knowledgeable about AUB regulations and policies governing this research, and who were acknowledged officially by the IRB. |[ ]
| Meeting recognized standards for safety when utilizing certain equipment, facilities, and procedures related to this research and providing documentation to the IRB |[ ]
| Not initiating any change or modification in the approved research without prior IRB approval, except when it is necessary to eliminate apparent immediate hazards to the participating subjects. In this case, I will be reporting to the IRB this modification within **two** business days to enable the IRB to decide that the modification is done to preserve the participants’/ subjects’ welfare and safety. |[ ]
| Reporting unexpected problems and risks involving human subjects to the IRB promptly. |[ ]
| Promptly complying with IRB’s decision to stop or discontinue the research, including the analysis of data already collected unless specifically approved by the IRB.  |[ ]
| Complying with the continuing review requirements of the IRB. Specifically, obtaining approval for continuing with the study before the initial approved period of the study expires. I understand that if I fail to apply for continuing IRB review and approval within the approval period, IRB-approval of the study will automatically terminate and all activities must cease, including analysis of previously collected data, until IRB approval is granted. |[ ]
| Maintaining accurate and complete research records including all informed consent documents, for at least 3 years from the completion of the research project. | [ ]  |
| Fully informing the IRB of all locations in which participants/subjects will be recruited for this study and being responsible for obtaining and maintaining IRB approvals and letters of cooperation from non-AUB sites. |[ ]
| Facilitating site visits and audits for evaluating and monitoring the research activities by certain authorized bodies. | [ ]  |
| Ensuring that if PI is unavailable due to reasons such as sabbatical or other type of leave, the PI will submit arrangements for conducting the study to the IRB, including the appointment of a temporary PI at AUB during the PI’s absence. | [ ]  |
| Ensuring that all personnel and investigators are aware of this research and have approved this submission. |[ ]

|  |
| --- |
| I certify that the above information is correct |
| Printed Name of Principal Investigator: Date:Click or tap to enter a date.Signature:  |  |

|  |
| --- |
| As department chairperson/dean of research, I acknowledge that this research is in keeping with the standards of my department and I assure that the principal investigator has met all departmental requirements for review and approval of this research.Printed Name of Department Chairperson / Dean of the Faculty or RepresentativeDate: Click or tap to enter a date.Signature: |

# Appendix I

**Notes:**

1. **In relation to section 3, “Abstract”**: This section is MANDATORY as the IRB is not requesting and will not review a separately submitted proposal.
2. **In relation to question 4.3:** It is crucial to ensure that the timeframe proposed to review patient charts aligns with the dates of their hospital visits/admissions, rather than being based on the period during which the research review will be conducted.
3. **In relation to question 5.3**: When the data source is records from the American University of Beirut Medical Center (AUBMC), please include Medical Record Number (MRN) as a variable within the data collection sheet to facilitate the preparation of reports by AUBHealth following the approval of the IRB.
4. **In relation to question 5.4:** When the data source records from the American University of Beirut Medical Center (AUBMC)**, it is essential to specify that the online form** “I Need Data and Reports” will be completed following IRB approval. This step will allow you to obtain authorization to access patient data from AUBMC. The form Is accessible via the AUBMC HIS Portal (<https://his.aub.edu.lb>).
5. **In relation to question 5.4:** Refer to the below terms to guide you on data handling and storage.
	* **Coded:** Direct personal identifiers have been removed and replaced with words, letters, figures, symbols, or a combination of these (not derived from or related to personal information) for purposes of protecting the identity of the source(s); but the original identifiers are retained in such a way that they can be traced back to the source(s) by someone with the code. Note: A code is sometimes also referred to as a “key,” “link,” or “map.”
	* **De-identified:** All direct personal identifiers are permanently removed, no code or key exists to link the information or materials to their original source(s), and the remaining information cannot reasonably be used by anyone to identify the source(s). Note: Protected health information is de-identified when it does not contain any of the 18 identifiers.  For more information, including the list of identifiers that must be removed to de-identify health information, see Request to create a de-identified dataset from research data. that is posted on the website. <https://www.aub.edu.lb/irb/Pages/applicationssubmission.aspx>
	* **Anonymous data:** Unidentified (i.e., personally identifiable information was not collected, or if collected, identifiers were not retained and cannot be retrieved); information that cannot be linked directly or indirectly by anyone to their source(s).
6. **In relation to question 5.5: It is essential to identify** the person(s) who will have access to the data and whose computer/desktop/laptop will be used for data storage.
7. **In relation to question 5.10: It is important to note that** according to AUB archiving policy, data must be stored for a minimum of 3 years after study completion. Specify how long you plan on keeping the data by taking into consideration this policy.
8. **In relation to question 6.3:** Refer to some of the reasons that might affect the practicability of obtaining consent.
* The sample size required is so large (e.g. population–based studies and epidemiology trials) that including only those records/data for which consent can be obtained would prohibit conclusions to be drawn, or would bias the sample such that conclusions would be skewed.
* The subjects for whom records would be reviewed are no longer followed and may be lost for follow-up.
* There is a risk of inflicting psychological, social, or other harm by contacting individuals or families.
* Research looking at issues such as outcomes/morbidity data where not having access to all subjects would affect the statistical outcome.
* Researcher not involved in the clinical care of the patient/subject.
1. After securing IRB approval, any additional changes to the stated research or research personnel need to be communicated to the IRB for review and approval.

