** American University of Beirut**

**Institutional Review Board**

**Request for Approval of Medical Record Review**

**Questions to determine if the study qualifies as a Retrospective Medical Record Review:**

1. Will the medical information to be accessed be limited to ONLY records of deceased?





1. Will the information collected be used to create a data archive for future research?





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?





If you answered “No” to all of the above questions, complete the section below.

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| --- |
| **The form must be completely filled without any deletions or alterations to the pre-printed content; as otherwise this will disqualify the submission and the application will not be processed.**  **Please refer to the notes section at the end of the form to guide you while filling the application.** |

**Request for Approval of Medical Record Review**

|  |  |
| --- | --- |
| **Date of Submission** | Choose Date |
| **Title of Research Project** | Click here to enter title |

**A. Principal Investigator:**

|  |  |  |
| --- | --- | --- |
| Name | Degree | Title |
| Enter Name | Enter Degree | Enter Title |
| Department | Faculty | Phone # |
| Enter Department | Enter Faculty | Enter Phone # |
| Pager #  Enter pager # | **CITI course certification:**  current | E-mail  Enter E-mail |
|  |

**B. Study Coordinator (if any):**

|  |  |  |
| --- | --- | --- |
| Name | Degree | Title |
| Enter Name | Enter Degree | Enter Title |
| Department | Faculty | Phone # |
| Enter Department | Enter Faculty | Enter Phone # |
| Pager #  Enter pager | **CITI course certification:**  current | E-mail  Enter pager |
|  |

**C. Key Study Personnel – include all people responsible for the design and conduct of the study (for collaborators from other institutions fill section “D”)**

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Dept. or Affiliation | Role in Study | **CITI course certification:** current |
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**D. Collaborators and IRB involvement at other institutions**

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| --- | --- | --- | --- |
| Name | Affiliation | Role in Study | CITI course /equivalent training course |
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***Project Description and Plan***

1. Funding source: (Specify intramural, departmental/divisional, governmental, NGO, Private, Industry, etc. or note unfunded otherwise)

Click here to enter funding source

1. Is this application being submitted as part of FRRP requirements?

 

1. Purpose of the study: Proposal/Abstract: Provide a brief description (limit to 250 words) including:

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

Click here to provide a brief description.

1. Estimated number of subjects whose information will be reviewed:

Click here to enter estimated number of subjects

1. Criteria for inclusion/exclusion:

Click here to enter criteria.

1. Probable Duration of study: (Please state the expected duration of the project, including all data analysis activities. Please remember that you will need to submit a continuing review form annually until study is closed and all analysis have been completed.)

Click here to enter probable duration of study.

1. Indicate the time period for record review (month & year\*).

Records from: Choose From Date To: Choose To Date

\*Kindly note that retrospective review projects are restricted to existing data on the **date of IRB submission**. Any information entered in or any record part of the medical record beyond the date of submission cannot be reviewed as part of this retrospective review research activity. **Doing so is considered a major violation of IRB and AUB policies and regulation.**

1. What information will be collected and recorded?
   * Specify the source of the information to be collected (e.g. Paper Medical Charts, Electronic Health Records, Pathology slides, Diagnostic Radiology material etc.)

Click here to specify the source.

* + Governing entity for the data source being accessed:
    - Medical records department (Electronic or paper medical records, pathology, radiology, etc.)
    - Approved Quality Improvement/Quality Assurance data sets

Click here to enter text.

\***Please note that 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**.

* + Please include a copy of your data collection tool, listing all variables to be extracted. **Only those items listed on this tool may be extracted by 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.

***Note: Investigators are reminded that subject identifiers and the means to link subject names and codes with research data should not be stored on unsecured moveable storage devices.  Identifiers and code keys must be stored in a secure manner.  If identifiers are stored on moveable storage media, it is the responsibility of the Principle Investigator to use or ensure the use of appropriate methods to protect access to these files.***

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

Click here to enter text.

* + Indicate who will have access to the data, and how access to the data storage (whether

paper-based or electronic) will be monitored.

Click 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?







If yes, describe the nature of this relationship.

Click here to describe the nature of this relationship.

1. Will information be collected from sources outside AUBMC (e.g. UHS, Private clinics of physicians affiliated to AUB/AUBMC, etc.)? 

If yes, please indicate name and location

Click here to indicate name and location.

1. Will information be collected from outside sites or countries? 

If yes, please indicate name and location:

Click here to indicate name and location.

***\*Note: This will require the submission of additional documents including IRB/administrative approval from outside sites.***

1. Will information be shared with outside entities?  

If yes, please indicate name and location:

Click here to indicate name and location.

***\*Note: Investigators are reminded that separate agreements for sharing data need to be executed before sharing any AUB/AUBMC data with outside entities. These agreements can be completed through the Office of Grants and Contracts and are required before final IRB approval letter is released.***

1. How will the data and/or identifiers be destroyed when no longer needed for research purposes?

If it will not be destroyed, please explain why identified data must be retained, for how long and how it will be secured.

Click here to enter explain.

For more information about de-identifying the data, please refer to the below link:

Link to de-identifying list on IRB Website

1. Waiver of Consent: Complete the following:

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

Please elaborate

Click here to elaborate.

* Will the waiver adversely affect subjects’ rights and welfare? 

Please elaborate

Click here to elaborate.

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

Click here to enter text.

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

If yes, please explain

Click here to explain.

How will pertinent information be returned to subjects, if appropriate at a later date?

Click here to enter text.

1. Personal/Financial Interest:

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

Click here to enter text.

1. Bibliography and References:

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

Click here to list up to five publications.

**Principal Investigator’s Assurance Statement**

* 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, 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 the informed consent form and/or any other documents to the IRB for approval prior to applying those changes in the study.
* I agree to abide by the policies and procedures of the AUB HRPP/IRB regarding the protection of human subjects including, but not limited to:
  + Ensuring that all personnel involved in the study have completed the human subjects training online course
  + Ensuring that the study will be conducted by qualified personnel only
  + Promptly complying with IRB decision to stop or discontinue the research
  + Obtaining approval for continuing with the study after the end of the approval period by submitting a request for renewal before the study expires. I understand that if I fail to apply for renewal, the study will automatically expire and all activity must cease until IRB approval is granted.
  + Maintain accurate and complete research records including all informed consent documents, for at least 3 years from the date of study completion
  + Fully informing the IRB of all locations in which records will be reviewed for this study, and being responsible for obtaining and maintaining IRB approvals and/or letters of administrative approvals from non-AUB sites.
  + The research will be performed according to ethical principles and in compliance with all prevailing and applicable laws, rules and regulations and policies regarding the protection of human subjects and research conduct.
  + Subject privacy and data confidentiality will be of paramount concern at all times, and every effort will be made to protect subjects’ rights and welfare

**By signing this protocol application, the investigator assures that the protected health information for which a Waiver of Authorization has been requested will not be reused or disclosed to any person or entity other than those listed in this application, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by the IRB.**

|  |  |  |
| --- | --- | --- |
|  |  | Enter Date |
| Principal Investigator’s Signature |  | Date |
| Department Chair’s Name |  | Enter Date |
| Department Chair’s Name and Signature |  | Date |

**Notes:**

1. **Under section 3, purpose of the study: Proposal/Abstract**, This section is MANDATORY as the IRB is not requesting and will not review a separately submitted proposal.
2. **Under section 7, indicate the time period for record review (month & year\*)**. It is essential that the period of interest for the review of charts reflects the dates of patients’ hospital visits/admissions and NOT the period of conducting the review for the stated research.
3. **Under section 8, what information will be collected and recorded**, Once IRB approval has been granted, the online form “I Need Data and Reports” needs to be completed in order to be granted access to AUBMC patient data for conducting the approved research. The form can be accessed through the AUBMC HIS Portal (<https://his.aub.edu.lb>).
4. **Under section 8, identify how data will be collected/recorded and state the plans for maintaining confidentiality and security of the data.** It is important to understand the differences between the methodical terms “coded”, “de-identified’ and “anonymous”, to select the one that is most appropriate method of review for your research:
   * **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 the 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, clinical data or other identified data source form that is posted on the website.
   * **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).
5. **Under section 8, indicate who will have access to the data, and how access to the data storage (whether paper-based or electronic) will be monitored**. The person/s who will have access to the data and whose computer/desktop/laptop will be used for data storage should be identified.
6. **Under section 13, how will the data and/or identifiers be destroyed when no longer needed for research purposes**, 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.
7. **Under section 14, describe why it would be impracticable to obtain the subjects consent and authorization for use or disclosure without the waiver**, some of the reasons that might affect the practicability of obtaining consent are as follows.

* The sample size required is so large (e.g. population –based studies, epidemiology trials) that including only those records/data for which consent can be obtained would prohibit conclusions to be drawn or 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 to 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.