1. **Policy**

1.1. The American University of Beirut (AUB) and American University of Beirut Medical Center (AUBMC) carry out scientific and clinical research to advance medical knowledge, patient care and to provide patients with opportunities of using investigational treatments and devices outside the standard of care.

1.2. Scientific and clinical research to be conducted at AUBMC shall undergo rigorous evaluation for scientific merit, and for protecting the rights and welfare of subjects/participants who will partake in these researches.

1.3. The Institutional Review Board (IRB) is the committee formally designated to review the conduct of research to protect the rights, safety and well-being of all human subjects recruited to participate in research activities conducted at AUB and/or by AUB faculty, students and staff, regardless of funding source. The primary mission of the IRB is to protect the rights, welfare and privacy of all individuals participating in biomedical, social, and behavioral research activities, including field or off-site research, as conducted by AUB faculty, staff and students. The IRB has the authority to approve, require modifications to the research in order to secure approval, defer, or disapprove any research activities.

1.4. Research involving human subjects can only be initiated at AUB or AUBMC after having IRB approval.

1.5. AUB IRB is the only IRB entitled to approve research involving human subjects/participants to be conducted at AUB/AUBMC premises or by AUB/AUBMC faculty.

1.6. In case adult subjects are assessed to be incapable of providing fully informed and legally effective consent, their legally authorized representative (LAR) may be approached for recruitment and consenting. Otherwise, research subjects/participants shall provide consent to participate in a research study for themselves.

1.7. In case research subjects/participants are under the legal age (18 years), legally effective informed consent to participate in research shall be required from their parents or authorized guardians. Furthermore, an assent, using age appropriate assent form as defined by the IRB, is required for children aged between 7 and 17 years but only after obtaining parental consent.
2. **Purpose**

2.1. To provide guidelines for the medical staff on the process of informing their patients about research protocols and that of enrolling them in research studies.

2.2. To highlight the patients’ rights when enrolled in research protocols, according to AUB Human Research Protection Program (HRPP) and Institutional Review Board (IRB) policies as well as applicable laws and regulations.

2.3. To document the patients’ enrollment in a research protocol in the patients’ electronic health records at AUBMC.

3. **Definitions**

3.1. **AUBHealth Electronic Medical Record (EMR):** Health Information system adopted by AUBMC.

3.2. **Human Research Subjects/Participants:** Patients recruited to research studies are referred to as human research subjects/participants and are protected by institutional regulations and by national laws besides their rights as patients. The words subject and participant can be used interchangeably in this policy.

3.3. **Institutional Review Board (IRB):** is the committee formally designated to review the conduct of research to protect the rights, safety and well-being of all human subjects recruited to participate in research activities conducted at AUB and/or by AUB faculty, students and staff, regardless of funding source. The primary mission of the IRB is to protect the rights, welfare and privacy of all individuals participating in biomedical, social, and behavioral research activities, including field or off-site research, as conducted by AUB faculty, staff and students.

3.4. **Human Research Protection Program (HRPP):** The program at AUB which oversees the safety and welfare of participants in research involving human subjects in accordance with all applicable country laws, institutional policies, and federal law when applicable.

3.5. **Clinical Research:** a research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or designee) directly interacts with human subjects.

3.6. **Clinical Trial:** a research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

3.7. **Principal Investigator (PI):** An individual authorized by HRPP/IRB at AUB to conduct a research project or program, and in accordance with AUBMC policy “Non-AUBMC Staff Participating in Clinical Research” (**HRP-MUL-001**). He/she shall be responsible and held accountable for the proper ethical conduct of a project or program, including the actions of all his/her research team members during any research activity involving human subjects taking place at AUBMC.

3.8. **Legally Authorized Representative (LAR):** an individual or judicial or other body authorized under applicable law to consent on behalf of a
prospective subject to the subject’s participation in the procedure(s) involved in the research

3.9. **Children** are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

3.10. **Assent** means a child’s affirmative agreement to participate in research. Mere failure to object shall not, absent affirmative agreement, be construed as assent.

4. **Procedure**

4.1. **Participants identification, initial approach and recruitment:**

4.1.1 Patients at AUBMC might be approached as potential participants if they meet the eligibility criteria for an ongoing research study initially by their physician or a member of the treatment team who is justifiably knowledgeable of their conditions.

a. In case potential participants are children who have not reached the legal age for consent (18 years), their parents or authorized guardian shall be approached first for permission and recruitment, except under very special circumstances and upon approval of AUBMC Administration, Research Affairs Office, AUB HRPP and AUB IRB.

b. Recruited participants shall stay under the care of the treating physician who approached them for recruitment irrespective of who the principal investigator responsible for conduct of research is.

c. AUBHealth EMR can also identify a patient as eligible to be enrolled in a certain study based on his/her medical record information. The EMR alerts the primary physician. Eligible patients might also be approached through the MyAUBHealth online health management application after approval by the AUB IRB. Patients at AUBMC can also become aware about ongoing research studies at the medical center from advertisements/flyers posted in various areas within the premise of AUB or AUBMC, from the public electronic platforms of the institution or through other means as approved by the AUB IRB.

4.2. **Informed Consent process and documentation**

4.2.1. **General requirements:**

a. Legally effective informed consent shall be required for participants who are capable to provide “an informed consent” and who have expressed their interest and agreed to participate in a research study upon approach and before recruitment.

b. Legally effective informed consent shall be required from parents or authorized guardians giving their permission upon approach to recruit their children who have not reached the legal age (18 years) as required and instructed by the IRB. Furthermore, an assent, using age appropriate assent form as defined by the IRB, is required for children aged between 7 and 17 years but only after obtaining parental consent.

c. Legally effective informed consent shall be required from a legally authorized representative (LAR) when the research participant is not capable to provide an “informed consent”. This includes participants who have cognitive impairment like dementia, mental challenges or disabilities…..
d. A witnessed legally effective consent shall be required when the research participant is illiterate, blind or visually impaired that hinders the participant to read.

e. A translator who speaks a language understood by the subject/LAR and witness shall be required in case the subject/LAR does not fully understand or read Arabic or English. The translator can be a member of the research team, a family member or a friend of the subject/LAR. The witness can be a family member or a friend of the subject/LAR; but shall not be a member of the research team.

4.3. **Setting and Context:**

4.3.1. The informed consent process shall be conducted by qualified personnel on the research team who is trained on the research protocol and is authorized by the IRB after fulfilling research ethics training as required by the institution. In case the person obtaining consent has any relationship with the patient, measures to protect against undue influence or coercion shall be considered.

4.3.2. The consenting process shall be conducted after IRB approval of the research study and before any research related procedure/intervention.

4.3.3. The consenting process shall be conducted at the appropriate time and condition (participants shall not be consented when in pain, labor, emotional distress, sedated,…).

4.3.4. The consenting process shall be conducted in an appropriate private, quiet, safe and comfortable setting.

4.4. **The informed consent process and elements:**

4.4.1. Participants/LAR shall be informed that there is a rigorous process that evaluates all research protocols weighing their risks and benefits before their implementation. Contact information of the HRPP/IRB shall be given to the participant for additional information about his/her rights as human research participant and for any complaints.

4.4.2. Participants/LAR shall be provided with a clear explanation about the study. The explanation shall be in lay language, and include the research purpose, procedures, duration of subject’s participation and identification of procedures that are experimental.

4.4.3. Participants/LAR shall be informed and they shall understand that their participation in a research study is completely voluntary and they can withdraw from the study at any time and that refusal to participate or withdrawal will involve no penalty or loss of benefits to which the participant is otherwise entitled at AUB or AUBMC.

4.4.4. Participants/LAR shall be provided with detailed explanation about any reasonably foreseeable risks or discomforts, and any benefits to the subject or to others which may reasonably be expected from the research shall be provided to subject prior to recruitment.

4.4.5. Participants/LAR shall be informed about alternative procedure(s) or treatment(s) that might be advantageous to them. The participants/LAR shall also be informed if no alternative procedure (s) or treatment(s) are available.

4.4.6. Participants/LAR shall be informed about the compensation for research related injuries and adverse events as detailed in the informed consent document.

4.4.7. Participants/LAR shall be provided with the contact details on whom to refer to for research-related questions and injury or adverse events reporting.
4.4.8. Participants/LAR shall be assured that their participation and identifiable information shall remain confidential and access to their records is limited to the research team, the clinical team caring for the patient and the office of the human research protection program and the institutional review board.

4.4.9. Participants/LAR shall be encouraged to ask questions about the research study and given ample time to consider participation, before consenting.

4.5. The informed consent documentation:

4.5.1. The most updated IRB approved and stamped version of the informed consent document shall be used.

4.5.2. If the participant/LAR agrees to participate in the research study, his/her signature shall be obtained on the informed consent document unless the IRB has waived written documentation of informed consent. The participant/LAR shall sign and personally date and time the informed consent document.

4.5.3. The participant/LAR shall be provided with a copy of the signed and dated informed consent document. The original signed and dated informed consent document shall be archived under the jurisdiction of the PI in the research study file. If photocopying the signed informed consent document is not feasible, then two original copies shall be signed.

4.6. Oral consent

4.6.1. When approved by the AUB IRB, an oral consent can be used.

4.6.2. The AUB IRB shall approve a written summary (script) of what is to be said to the participant or LAR.

4.6.3. The script includes the elements of informed consent that will be orally presented to the participant or the LAR as approved by the AUB IRB.

4.6.4. The person actually obtaining the oral consent shall document the consent of each participant/LAR on the consent script form approved and/or stamped by the IRB. The form shall include the name of the participant/LAR in addition to the name and signature of the person obtaining the consent and the date and time of the consent.

4.6.5. The signed form for each patient shall be kept in the study file.

4.6.6. A copy of the summary/script can be given to the participant/LAR when possible.

4.7. Re-Consent and/or Notification of Significant New Findings that Develop During the Course of Research:

4.7.1. Informed consent is an ongoing process. The Principal Investigator (PI) is required to inform research participants about any significant new findings developed during the course of the research study or any change that might relate to the research participants' willingness to continue participation (45 CFR 46.116(b)(5)).

4.7.2. The PI shall make an initial determination whether new information shall be communicated to current and/or previously enrolled study participants and decide on the most appropriate form of communication.

4.7.3. These notifications may include but are not limited to:

a. New information regarding the risks of the study.

b. The addition of new study procedures to prevent a newly discovered harm.

c. A change in available alternatives, such as new FDA approval of medications used in the study.

d. Some of these changes may simply require a notification to a subset of study participants (e.g., those on study intervention only) or all
study participants (including those who concluded their participation).
e. If a substantial period of time has elapsed between the time consent was obtained and the study initiation, it might be necessary to ensure that subjects still want to participate in the research. For example, the prospective subject may no longer be interested in participating, may no longer meet the eligibility criteria, may no longer find the risks acceptable, or may no longer have the time to complete all study-related activities.
f. A new consent form may need to be signed by the participants who are willing to continue in the study. Accordingly, modification to the consent form and the protocol must be submitted for the IRB review. The amendment request should include a plan for re-consenting study participants or rationale for no further action being requested. Participants should provide their consent prior to their involvement in the procedural change.

4.8. AUBMC Research affairs approval and Registration of a research study on the AUBHealth EMR:
   4.8.1. When a PI or a research team gains the approval of AUB IRB and AUBMC research affairs office for a research study, a member of the research affairs office or AUBHealth team shall create the research study record on the AUBHealth EMR (research application). The research study shall then be activated on the AUBHealth EMR.
   4.8.2. The research study team shall be listed on the study users and providers form and given access to the study records.
   4.8.3. Only the research team members listed on the study record shall be granted access to edit entries in the research study record on the EMR.

4.9. Enrollment of Patients in activated Research studies on AUBHealth research application:
   4.9.1. Once the study is activated, eligible and interested patients can be scheduled, enrolled and associated to the active research studies after securing informed consent as defined in section 4.2 of this policy.
   4.9.2. The status of the patient shall be updated on AUBHealth Research application (consented and enrolled). A note can be added in the comment box.
   4.9.3. When placing a medical order related to the research study, the following is required:
      a. A medical doctor (attending physician, research fellow, clinical fellow, or resident) shall open a patient encounter on the EMR.
      b. The medical doctor shall select the orders to be placed for this encounter and enter order-specific information.
      c. The medical doctor shall then open order-study association grid and indicate study-related orders.
      d. The PI, co-Investigator or authorized research team member with order signing privileges shall verify and sign the orders.
      e. The PI/research team shall be notified of results provided that the orders are linked to the study.
   4.9.4. Patients enrolled in an interventional research study at AUBMC shall have a research tag on their electronic medical record. Whenever the electronic medical chart of such a patient is opened, the research tag shall show on his/her EMR to notify the caregiver(s) that the patient is enrolled in a research study.
4.9.5. Once the subject’s participation comes to an end, or once the subject chooses to withdraw from the study, the PI or his/her designated person shall update the patient’s study enrollment record status on the patient’s chart. The research tag shall disappear in 30 days after the end date of the patient’s participation.

4.10. Documentation of Research encounters on AUBHealth Research application:

4.10.1. A patient enrolled in a research study shall be linked to the related active research study on AUBHealth research application.

4.10.2. Patient encounters for research purposes shall be logged on AUBHealth EMR; and those encounters shall be linked to the related research study.

4.10.3. Regular clinic visits that include research component shall be linked to the related research study. Physicians shall document the encounter in a medical progress note. He/she or any member of the research team shall also document the research component of the encounter on a research note through the research activity/navigator. Research notes written by the research team (other than the PI) shall be co-signed by the PI.

4.10.4. A copy of the signed informed consent form shall be sent to the medical record to be scanned and uploaded to the patient AUBHealth EMR. The original signed informed consent form shall stay in the research study file under the responsibility of the PI.

4.11. Deactivating a study on the AUBHealth Research application.

4.11.1. Once the study is closed, the Research Affairs Office shall be notified by the IRB.

4.11.2. The Research Affairs Office/AUBHealth research analyst shall change the status of the study to “Completed”.

4.11.3. The research-related security accesses granted in the EMR to the research team members shall be deactivated.

4.11.4. Research study shall not be deactivated if any of the participant statuses is still active.

4.11.5. Research Affairs Office can continue to retrieve study information.

5. Responsibilities

5.1. Principal Investigator (PI): Has the ultimate responsibility for the conduct of the study, the ethical performance of the research team, the protection of the rights and welfare of human subjects involved in the research, and strict adherence to any stipulations imposed by the IRB. The PI shall:

5.1.1. Secure AUB IRB approval and AUBMC clearance prior to initiation of any research involving human subjects at AUBMC.

5.1.2. Be familiar and adhere to institutional policies, applicable national laws and applicable US Federal regulations for federally sponsored research, relevant to the conduct of research involving human subjects, and FDA regulations governing clinical research where applicable.

5.1.3. Complete the human subjects’ protection ethical training (CITI training), as required by the HRPP/IRB, and any other requirements to conduct research at AUB/AUBMC.

5.1.4. Ensure that all research personnel are qualified, appropriately trained, have completed institutional requirements and trainings to conduct research involving human subjects, are acknowledged by the AUB IRB and will adhere to the provisions of the approved protocol.
5.1.5. Have a thorough understanding of the protocol including risks and adverse events, including those associated with the drug or device under investigation, if applicable.

5.1.6. Ensure that he/she or an appropriately trained (including CITI certification) designee explains the protocol to subject/legally authorized individual and seeks informed consent/assent as outlined in the HRPP/IRB policies and procedures, and as approved by the IRB.

5.1.7. Ensure that only IRB approved and stamped consent and assent documents are used in the study.

5.1.8. Oversee the adequate conduct of the research study (by the research team) in terms of:
   a. Adhering to IRB approved protocol and to any stipulations required by the IRB.
   b. Adhering to inclusion/exclusion criteria.
   c. Identifying, approaching and recruiting Participants.
   d. Consenting process and documentation.
   e. Keeping a log of participants enrolled in the research study.
   f. Collecting Data and following up on research participants.
   g. Keeping track and managing adverse events related to the research study.
   h. Documenting of research encounters.
   i. Adequate record keeping of all research study documents and records.
   j. Communication with the research team members.

5.1.9. Promptly report to the IRB any changes in research activity during the approval period, such as amendments in protocol or consent form, and shall implement no changes in the approved protocol or consent without prior IRB approval, except in an emergency if necessary to safeguard the well-being of human subjects, and in such event will notify IRB within two business days.

5.1.10.Promptly report to the IRB new information that may adversely affect the safety of subjects/participants and the conduct of research.

5.1.11. Comply with the IRB’s continuing review and re-approval requirements, as stipulated in the IRB-approved protocol, including reports of those unanticipated problems which did not require prompt reporting to the IRB.

5.1.12. Report to the IRB any Internal and external Adverse Event(s) as per the delineated policies and procedures (Unanticipated Problem Involving Risks to Subjects or Others (UPIRSOs)).

5.1.13. Report to the IRB any problems or incidents, related to the conduct of a study or subject participation, including those in the recruitment or consent process.

5.1.14. Report to the IRB any violation of a research protocol or any use of subjects not approved by the IRB.

5.1.15. Ensure and verify the documentation of participant/subject enrollment in interventional and clinical research trials on AUBHealth Research application.

5.1.16. Secure adequate record keeping and storage of all research related documents.

5.1.17. Respond to subjects’ complaints and/or their requests for more information about the research study they are enrolled in.

5.1.18. Consider conflict of interests that might be related to the research participant or the outcome of the study which might affect the integrity of the human research activities. The PI shall disclose any real or perceived conflicts in accordance with AUB policy and comply with all conditions of
the AUB management plan and any/all additional management practices as may be stipulated by the IRB.

5.1.19. Advise the IRB when PI intends to be absent from AUB for extended period of time (e.g. sabbatical leave), designating an Interim PI or emergency point of contact in the absence of PI.

5.1.20. Submit timely notification to the IRB in the event the PI intends to leave AUB. All current approved IRB protocols shall either be transferred to a new PI by submission of an amendment to the existing protocol, which requires IRB review and approval before it can be considered effective; or terminated by the PI effective a designated date specified in writing to the IRB.

5.1.21. Advise co-investigators and all members of the research team of an Administrative Hold and the consequences of such a hold on recruitment, research conduct and data analysis, in the event a research study is placed on Administrative Hold (by PI).

5.1.22. Advise co-investigators and all members of the research team in the event a research study is suspended by the IRB, and the consequences of suspension on recruitment, research conduct and data analysis.

5.1.23. Adhere to the research study management requirements on AUBHealth Research Application:

5.1.24. Ensure that:
   a. All patient encounters related to the study are appropriately linked to the study record on AUBHealth Research Application.
   b. All Study related orders are linked to the study.
   c. All research visits information are documented in AUBHealth Research Application.
   d. Countersign notes documented by research team.

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6. **Signatures**

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5th edition prepared by:
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7. **References**

7.1. IRB manual
7.2. 21 CFR 50.20, 50.25, 50.27
7.3. 45 CFR 46.116, 46.117
7.4. National Institutes of Health (NIH)
7.5. World Health Organization
7.6. AUBHealth workflows and guides
7.7. AUBHealth Research learning home dashboard (LHD)
7.8. Unanticipated Problem Involving Risks to Subjects or Others (UPIRSOs), Form and Guiding Document

8. **Modifications**

8.1. Introducing AUBHealth EMR workflows to the policy.
8.2. Detailing the section on informed consent process
8.3. Adding the research documentation section
8.4. Adding some elements to the policy section.
8.5. Adding the section on “Participants identification, initial approach and recruitment”