Issue Date
31.03.2017
Quality, Accreditation and Risk Management Department

Title:	**Human Subject Research at AUBMC**	Index Number:	**HRP-MUL-005** (Func. - Categ. - Sr.No.)
Function:	**Human Subject Research Program**	Category:	**Multidisciplinary**
Scope of application:	**All AUBMC Departments / Sections / Units**	Original Date: **08.03.2017**	Next Review Date: **08.03.2019**

1. *Policy*

1.1. The Medical Center Director shall delegate the governance of research at the Medical Center to the Associate Medical Center Director for Research Affairs.

1.2. AUBMC shall only permit the conduction of interventional and non-interventional Biomedical research studies and Social and Behavioral Sciences (SBS) research studies involving human subjects that are approved by the American University of Beirut (AUB) Institutional Review Board (IRB).

1.3. All AUBMC premises shall be eligible research sites, and defined in individual research protocols that are reviewed and approved by the AUB IRB, the AUB Human Research Protection Program (HRPP) Director, and cleared by the Associate Medical Center Director for Research Affairs.

1.4. Participation of staff members in any research study shall be totally voluntary and neither the Principal Investigators (PI) nor supervisor or any AUB/AUBMC faculty or staff members can in any way force or coerce a staff member or patient to participate.

1.5. As per policy "Non-AUBMC Staff Participating in Clinical Research ***(HRP-MUL-001)***", active AUBMC medical staff members can serve as PIs or Co-Investigators on any research project involving human subjects carried out at the medical center. This policy shall grant an exception to full-time faculty members at Hariri School of Nursing (HSON) conducting projects that are approved by the Biomedical or the Social and Behavioral Sciences (SBS) AUB-IRB. Exceptions to this policy require approval of the AUB HRPP Director and Associate Medical Center Director for Research Affairs.

1.6. Research Fellows (RFs) at AUBMC shall hold a medical degree; and Research Assistants (RA) shall hold Bachelor or Master Degree. They can serve as either co-investigators or research staff and function under the direct supervision of the PI. AUB students can also serve on research teams in a role similar to Research assistants.

2. *Purpose*

2.1. Define the governance, management and scope of human subject research at AUBMC.

2.2. Specify the facilities permitted for use in human subject research At AUBMC.

2.3. Delineate the AUBMC staff participation in human subject research conducted at AUBMC.

2.4. Define the eligibility and qualifications of faculty and staff involved in the conduct of human subject research at AUBMC.

2.5. Delineate the reporting channel of research related Adverse Events at AUBMC.

3. *Definitions*

3.1. **Adverse Event**: Any untoward or unfavorable medical occurrence in a participant, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participant's participation in the research, whether or not considered related to the participant's participation in the research.

3.2. **Co-Investigator:** An individual approved to help conduct a research project or program. For the purpose of this policy, a medical staff member or HSON faculty member assuming the required co-Investigator role shall be responsible and held accountable for upholding all AUBMC rules, regulations and policies in effect, and the compliance of all non-AUBMC research personnel involved in his/her research project.

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

3.4. **Human subject**: is defined as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information".

3.5. **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.

3.6. **Principal Investigator (PI):** An individual approved to direct a research project or program. 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.

3.7. **Research:** is defined as "a systematic investigation, including research development, testing and evaluation, which is designed (in whole or in part) to develop or contribute to generalizable knowledge"

3.8. **Sentinel Event:** An unanticipated occurrence involving death or major permanent loss of function or a serious psychological injury unrelated to the natural course of the patients' illness or underlying condition

4. Procedure

4.1. **Governance:**

4.1.1. The Associate Medical Center Director for Research Affairs shall report to the Medical Center Director in this capacity.

4.1.2. The Associate Medical Center Director for Research Affairs shall oversee, manage and permit the conduct of all research studies at AUBMC and shall ensure compliance with set forth and applicable laws, standards, regulation, policies and procedures. He/She shall coordinate with the HRPP and IRB offices.

4.1.3. The Associate Medical Center Director for Research Affairs shall consult the Medical Center Director, Chief of Staff, and other directors at AUBMC as appropriate for certain research projects on behalf of the PI before permitting the conduct of research projects at AUBMC.

4.1.4. The Associate Medical Center Director for Research Affairs updates the Medical Center Director on the research activities, including those involving human subject research, and any related concerns through monthly reports and special meetings.

4.2. **Scope of research at AUBMC**

4.2.1. Leadership in innovative research is at the core of AUBMC mission that is communicated with its faculty, staff and community and posted on its official website.

4.2.2. AUBMC administration shall permit the conduct of interventional and non-interventional biomedical research studies that involve drugs, medical devices and testing, in addition to retrospective medical records review after approval by the AUB IRB.

4.2.3. AUBMC also shall permit SBS research that deals with research studies concerned with behavioral methodology and analysis and that are approved by AUB IRB.

4.3. **Facilities and Resources for Research at AUBMC**

4.3.1. Associate Medical Center Director for Research Affairs shall act on the behalf of the Medical Center Director regarding the approval of the use of

AUBMC space for research purposes, the involvement of non-physician staff members as subjects or research staff, and the use of AUBMC resources and equipment, the access to databases, datasets, biobanks and specimen collections, media, medical records, administrative, operational and financial data, or any other data collection or material, patient-related or otherwise, at AUBMC.

4.3.2. Use of AUBMC resources/equipment for research shall be subject to additional approval by the Associate Medical Center Director for Research Affairs, after IRB approval, for certain protocols to ensure that operational and patient safety aspects are respected.

4.3.3. In case of AUBMC owned medical equipment are used:

a. The PI shall indicate the use of AUBMC owned equipment on the IRB application and complete the related AUBMC form (Request to Use Hospital Equipment & Resources for Research Projects" ***(Appendix 6.1)***.
b. The HRPP/IRB office shall send the completed form to the office of the Associate Medical Center Director for Research Affairs for processing.
c. The office of the Medical Center Research Affairs shall send the completed form to the Medical Engineering Department to ensure that adequate Preventive maintenance (PM) is performed on the mentioned equipment.
d. The Medical Engineering office shall report back to the office of the Medical Center Research Affairs, and the decision shall be communicated in turn to the HRPP/IRB office.
e. Simultaneously, the office of the Medical Center Research Affairs shall send the completed form to the financial office (AUBMC comptroller) to price the tests and/or procedures requested to be performed using AUBMC owned equipment. The rates shall then be sent to the office of Grants and Contracts (OGC) at AUB for inclusion in the budget as applicable. Release of final IRB approval shall be contingent on clearance of all financial matters related to the study.

4.3.4. In case the equipment used for research are non-AUBMC owned and provided by a research study sponsor or the Principal Investigator for research purposes:

a. The PI shall indicate the use of non-AUBMC owned equipment (sponsor or PI provided equipment) on the IRB application and complete the related form. The PI also shall indicate the duration expected for the use of the mentioned equipment.
b. The HRPP/IRB shall send the completed form to the office of the Associate Medical Center Director for Research Affairs for processing.
c. The office of the Medical Center Research Affairs shall send the completed form to the Medical Engineering Department.
d. The Medical Engineering office shall report back to the office of the Medical Center Research Affairs on safety and adequate PM, and the decision shall be communicated in turn to the HRPP/IRB office.

4.3.5. Simultaneously, the Medical Engineering shall enroll the mentioned equipment under the PM (as per policy "Medical Equipment Plan ***FMS-MEQ-001***) schedule for the specific period.

4.3.6. The PI shall inform the office of the Medical Center Research Affairs and the HRPP/IRB through continuing reviews and related amendment forms when the equipment is no more used for research purposes.

4.3.7. A flowchart that maps the above practice is delineated in ***Appendix 6.2***.

4.3.8. In case of AUBMC Pathology and Laboratory Medicine (PLM) Services are required for research:

a. PI shall indicate the need to use Pathology and Laboratory Medicine Services and indicate the type and code of test on the HRPP/IRB application and the related AUBMC form ***(Appendix 6.1)***.

b. The HRPP/IRB office shall send the form to the office of the Medical Center Research Affairs for review and for processing with the PLM administrative office and the AUBMC financial office (AUBMC Comptroller) for pricing.

c. The rates shall then be sent to OGC for inclusion in the budget as applicable. Release of final IRB approval shall be contingent on clearance of all financial matters related to the study.

4.3.9. In case AUBMC staff time is needed for research:

a. PI shall indicate the need to AUBMC staff time in his/her research study and specify what type of tasks and amount of staff time needed as instructed in ***Appendix 6.1***.

b. The HRPP/IRB office shall send the form to the office of the Medical Center Research Affairs for review for processing with the relevant administrative office (Nursing, clinical, non-clinical…) responsible for the concerned staff.

4.3.10. In case of AUBMC Pathology and Lab Medicine (PLM) Services are needed, the "**Request to Use Hospital Equipment, Services & Resources for Research Projects"** form should be completed and lab should be consulted for accounting the PLM services in the research study budget.

4.3.11. In case of formulary Medications and investigational drugs are needed for research: the pharmacy policy on" Investigational Drugs" MMU-PHA-615 shall be followed

4.4. Eligibility, qualification and requirements of Principle investigators and Research staff

4.4.1. Only active AUBMC medical faculty members can serve as Principal Investigators on any research project involving human subjects carried out at the medical center. This policy shall grant an exception to full-time faculty members at HSON conducting projects that are approved by the Medical Engineering or SBS AUB IRB as Exempt or Expedited, or studies approved by the SBS AUB IRB during a fully convened board meeting. Exceptions to this policy shall require approval of the AUB HRPP Director and Associate Medical Center Director for Research Affairs.

4.4.2. AUB Students who have research studies involving human subjects at the Medical Center can serve as co-investigators or research staff under the direct supervision of the PI.

4.4.3. Research Fellows (RFs) at AUBMC shall hold a medical degree and serve as co-investigators with the PI on research studies involving human subjects conducted at AUBMC.

4.4.4. Research assistants (RAs) shall be appointed, guided, supervised and evaluated by the PIs. They shall hold Bachelor or Master Degrees. They shall serve as co-Investigators or research staff.

4.4.5. PIs and any staff member involved in human subject research shall be required to take, pass and renew mandatory web-based courses administered by CITI (University of Miami), to which AUB has subscribed and is managed by AUB HRPP.

4.5. <u>AUBMC staff participation as research subjects:</u>

4.5.1. AUBMC staff members could be considered vulnerable subjects when it comes to their participation in certain human research conducted at the medical center.

4.5.2. Dealing with vulnerable subjects who might include employees in certain situations is defined in the AUB IRB manual, which shall serve as the guide governing research practice at AUB and AUBMC.

4.5.3. Participation of staff in any research study is totally voluntary and neither the PI nor supervisor or any AUBMC faculty or staff can in any way force or coerce a staff member to participate.

4.5.4. Participation of staff members as research subjects shall be reviewed on case by case basis by the IRB, like any study, taking into account the proposed protocol, level of risk, recruitment strategy, and safeguards put in place and presence of potential coercion or inappropriate influence.

4.5.5. For SBS IRB approved research studies that entail AUBMC staff (medical, nursing, technical, non-technical, and administrative) and medical students/residents to complete online surveys, the HRPP/IRB and in coordination with AUBMC administration have established a mechanism to ensure the faculty and staff email addresses from AUBMC for research purposes while securing confidentiality and restricted email use. Paper-based surveys shall not be permitted. The below steps shall be followed:

a. The PI shall send an official request to the IRB along with the IRB application and research protocol.
b. The PI shall specify the targeted population.
c. Only a percentage of a large group can be selected to be approached for research.
d. The office of the Associate Director Medical Center for Research Affairs shall secure approval from AUBMC concerned office depending on the faculty/staff category or role.
e. The medical center office responsible for the concerned staff shall process the request and send the approval along with the sample list of emails to the office of the Associate Medical Center Director for Research Affairs, and shall be in turn forwarded to the IRB office.
f. The IRB shall send the list of emails to Academic Core Processes & Systems (ACPS) that shall send the lime survey notification email to the specified list of emails without the involvement of the PI.
g. The PI shall receive the completed surveys anonymously.

4.6. <u>Sentinel/adverse events related to research at AUBMC</u>

4.6.1. The IRB shall receive Adverse Event (AE) form submitted by the PI.

4.6.2. The IRB shall notify the AUBMC administration through the Quality, Accreditation and Risk Management Department of the submitted research related Adverse Event occurring at AUBMC.

4.6.3. Quality, Accreditation and Risk Management Department shall review the reported AE, take notice of action taken by the IRB or request additional information.

4.6.4. The Patient Safety and Risk Manager shall assess the AE and quantify the harm and recommend covering the expenses of medical treatment associated with verified AE.

4.6.5. The Quality, Accreditation and Risk Management Department, shall inform the office of the Associate Medical Center Director for Research Affairs of any adverse event form that is submitted on a patient known to be enrolled in a research project. The Office shall inform the IRB who shall review and follow on the matter per established procedures.

4.7. Coverage of Research Related Injuries and adverse Events

4.7.1. All Interventional studies and clinical trials conducted at AUBMC are required to have insurance coverage for research related injuries and adverse events regardless of the study funding source.

4.7.2. Industry sponsored and funded studies shall have insurance coverage secured by the sponsor. Whenever applicable, non-profit organizations sponsoring a research study shall also provide insurance coverage.

4.7.3. PI-initiated studies at AUBMC shall have primary coverage by AUBMC for directly-related research injuries.

4.8. Management of waste generated by Research

4.8.1. Faculty and staff participating in research trials shall be required to follow AUBMC requirements and instructions regarding waste management set forth in related policies (Hazardous Material and Waste Management Plan ***FMS-HWM-001***) and attend related courses in this regard.

4.8.2. Biological waste generated from research studies shall be handled as per AUBMC policy (Hazardous Material and Waste Management Plan ***FMS-HWM-001***).

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5. *Signatures*

Prepared by	Name	Signature	Date
Executive Administrator, Human Research Protection Program	Jamale El Eid, MPH, PMP		8/3/2017
Reviewed and Concurred by	**Name**	**Signature**	**Date**
Associate Medical Center Director for Research Affairs / Director, Human Research Protection Program	Ali Abu-Alfa, MD		march 9, 2017
Chief Quality and Compliance Officer	Petra Khoury, Pharm D		27/3/17
Approved by	**Name**	**Signature**	**Date**
Chief of Staff	Samir Alam, MD		27/3/17
Medical Center Director and Chief Medical Officer	Hassan El Solh, MD		30/03/2017
Deputy EVP/Dean	Ziyad Ghazzal, MD		31/3/2017

6. *Appendices*

6.1. Request to Use Hospital Equipment, Services & Resources for Research Projects
6.2. Management of Equipment Use in Human Subject Research at AUBMC

7. *References:*

7.1. IRB manual
7.2. Non-AUBMC staff participating in Clinical Research (HRP-MUL-001)
7.3. Hazardous Material and Waste Management Plan (FMS-HWM-001)
7.4. Medical Equipment Plan ***FMS-MEQ-001***
7.5. ***Investigational Drugs*** MMU-PHA-615
7.6. ***ClinicalTrials.gov***

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Appendix 6.1

Request to Use Hospital Equipment, Services & Resources for Research Projects

1. Type of request (more than one item can apply)

   - Use of AUBMC owned equipment for research
   - Use of AUBMC services/procedure/tests for research
   - Use of non-AUBMC owned equipment for research
   - Use of AUBMC staff time for research
   - Use of AUBMC material for research
   - Waiver of all costs related to equipment, service, staff time and/or materials
   - Reduction of all costs related to equipment, service, staff time and/or materials

2. General Information

Principal Investigator's Name	
Department	
Protocol Name	
IRB Protocol Number	
IRB approval status	
Study starting date	
Expected ending date	

3. In case AUBMC owned Equipment is to be used

Type/Name of equipment	
Department/location	
Frequency of use per subject	
Duration of use per subject	
Number of subjects	
Comments	

4. In case non-AUBMC owned Equipment is to be used

Type/Name of Equipment	
Equipment Model	
Equipment Sponsor/provider	
Expected start of use for the study	
Expected End of use for the study	
Comments	

5. Services, procedures, Tests & materials to be used

Type of service/procedure/test	
AUBMC Code of test/service/procedure	
AUBMC rate (if known to PI)	
Are there any disposable items to be used in the test?	☐ Yes ☐ No If yes, please list:
Codes of disposable items *(if known to PI)*	
Comments	

6. Human Resources/staff time

Is there any clinical/nonclinical staff involvement?	☐ Yes ☐ No
Number of involved staff	
Name(s) of staff involved	
Tasks Required:	
Name of Supervisor or Director for involved staff members	
How you intend to Manage staff time between clinical care/job tasks & research tasks? Please Comment	
Is there any compensation for staff?	☐ Yes ☐ No
Amount of compensation	
How are you planning to cover this compensation?	

7. Funding resources

Do you have any type of funding resource?	☐Full ☐ Partial ☐ None
Name of funding source	
Amount of available funding	

8. The section below is to be completed by the Medical Engineering(ME) in case medical equipment are used

Equipment Name	AUBMC owned (yes/No)	If Yes- Preventive Maintenance(PM) is cleared (please indicate)	If No – ME safety check and PM is cleared (please indicate)

Medical Engineering Responsible Name and Signature Date:

9. The section below is to be completed by the AUBMC financial office

Test/procedure/service	AUBMC code	AUBMC unit rate	Quantity	Total Budget

Financial Comptroller Name and Signature: Date:

10. The section below is to be completed by the AUBMC HR/Nursing Director/Department Head as applicable

    Endorsement of the HR/Nursing Director/Department Head
    Name:_____
    □ Yes
    □ No
    Name & signature: ----------

OFFICE USE

11. Endorsement of the service Department Director or Chair

12. Service or Department Name:_____
    □ Yes
    □ No
    Name & signature: ----------

13. Endorsement of the service Department Director or Chair

14. Service or Department Name:_____
    □ Yes
    □ No
    Name & signature: ----------

15. Endorsement of the service Department Director or Chair

16. Service or Department Name:_____
    □ Yes
    □ No
    Name & signature: ----------

Comments: ----------

17. AUBMC Administration Decision

- ☐ Approval for:
  - Use of Equipment, service, staff time
  - Waiver of all costs related to equipment, services & materials
  - Reduction of all costs related to equipment & materials

    % reduction --------- or New rate----------
  - ☐

- ☐ Disapproval

Medical Center Associate Director for Research Affairs

Signature: ----------

Date:

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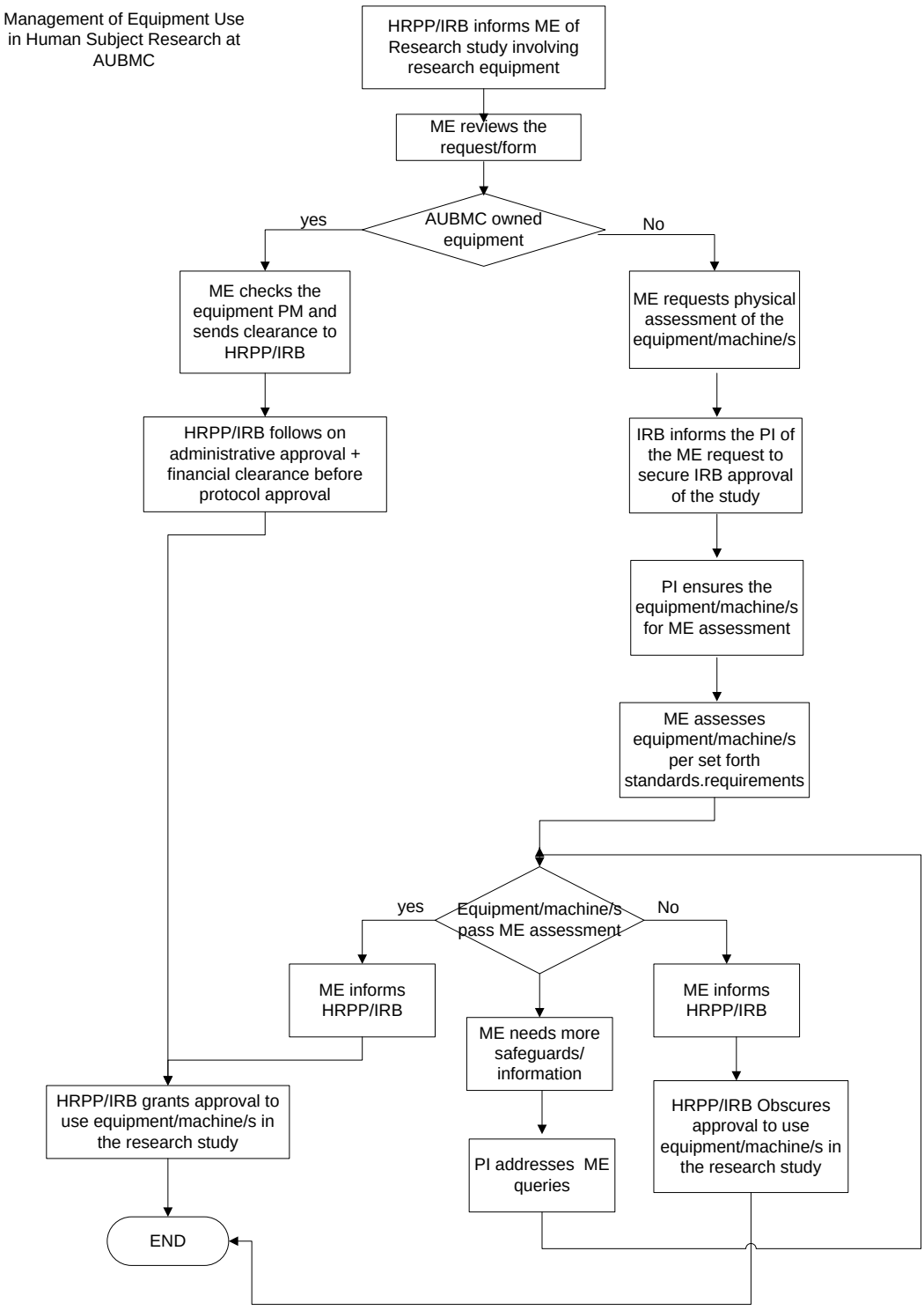
Appendix6.2

Management of Equipment Use in Human Subject Research at AUBMC



ME: Medical Engineering
HRPP: Human Research Protection Program
IRB: Institutional Review Board
PI: Principle Investigator