Title: Access to Medical Records for Research purposes

Index Number: HRP-MUL-003

Function: Human Subject Research Program

Category: Multidisciplinary

Scope of application:
- Medical Records Department
- AUB Clinical Research Center
- All Clinical Investigators
- All Patient Care Areas

Original Date: 07.09.2010

Reviewed on: 16.03.2017

Next Review Date: 16.03.2020

1. Policy

1.1. Accessing Patients’ medical records and individually identifiable health information at the American University of Beirut Medical Center (AUBMC) for research purposes is regulated by the AUB Institutional Review Board (IRB) and governed by the provisions of research protocols.

1.2. No access of Patients’ medical records and individually identifiable health information at the American University of Beirut Medical Center (AUBMC) for research purposes is allowed before securing AUB IRB approval.

1.3. It is the role of the AUB IRB to ensure that approved research protocols have adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

1.4. Failure to comply with AUB IRB requirements and regulations pertaining to accessing of individually identifiable health information and human research protection shall be prima fasciae evidence of a breach of AUB and AUBMC policies, and may lead, following investigation and due process, to suspension of IRB approval and other administrative actions.

2. Purpose

2.1. To provide guidelines for permitting access by Principal Investigators (PI) and research team members to medical records and individually identifiable health information for specified IRB approved research purposes.

3. Definitions

3.1. Human Research Subjects: Patients recruited to research studies are referred to as human research subjects and are protected by institutional regulations and by local laws besides their rights as patients.

3.2. 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.
3.3. Privacy: is the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

3.4. Confidentiality: pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

3.5. Medical Record / Health Record: it is a systematic documentation of a single patient’s medical history and care across time. It is considered the principal repository (storage area) for data and information about medical history and healthcare services provided to an individual patient. It documents the “who, what, when, where and how” of the patient care process. It includes but is not limited to paper, films, tracings and reports in electronic and hard copy.

3.6. Health Information: Any information, whether oral or recorded in any form or medium, that (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

3.7. Individually Identifiable Health Information: Information that is a subset of health information, including demographic information collected from an individual, and (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (a) that identifies the individual; or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

3.8. Principal Investigator: An individual authorized by HRPP/IRB at AUB to conduct a research project or program, and in accordance with AUBMC policy (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.

3.9. Research as Defined by DHHS: 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.

3.10. Research as Defined by USFDA: Any experiment that involves a test article and one or more Human Subjects, in which the results of the activity are intended to be later submitted to, or held for inspection by, the United States Food and Drug Administration as part of an application for a research or marketing permit.

4. Procedure

4.1. Principal Investigator, Co-Investigators and research personnel authorized by the AUB IRB shall protect subjects’ privacy and maintain confidentiality of individually identifiable health information when conducting research that involves human subjects and/or access to medical records.
4.2. Sponsor representatives and other representatives of regulatory agencies that might have access to medical records shall maintain confidentiality of data. Their site visit(s) and access to medical records shall be conducted in accordance with relevant regulations and applicable AUB/AUBMC policies.

4.3. Any access to medical records shall be restricted to the extent stipulated by the research protocol and/or Clinical Trial Agreements.

4.4. Informed consent shall be sought from subjects prior to access to their medical records for research purposes, or AUB IRB waiver of consent shall be secured prior to access as per relevant regulations.

4.5. Patient Information for research purposes are provided and controlled by the AUBMC Decision Support Unit per the AUB-IRB approval and recommendations.

4.6. **Access of Principal Investigator and/or his/her research team to medical records**
   4.6.1. Submit to the IRB your research protocol, application and all relevant documents.
   4.6.2. Secure IRB approval prior to research initiation.
   4.6.3. In case the IRB did not waive informed consent, carry out legally effective informed consent process and disclose to subject the safeguards to protect his/her privacy and confidentiality of his/her individually identifiable information. Get written informed consent if required by the IRB prior to accessing subject’s medical records.
   4.6.4. Request in writing from the Medical Record Administrator (or delegate) the subjects medical records indicating that your access is for research purposes.
   4.6.5. Provide to the Medical Record Administrator (or delegate) besides your request, copy of the IRB approval and documentation that you are research staff authorized by the IRB to access medical records for a specified research study.
   4.6.6. Follow the provisions of the research protocol in terms of accessing, recording and disclosing of individually identifiable health information as approved by the IRB.
   4.6.7. Act responsibly and proactively to protect the confidentiality of collected data and the privacy of recruited subjects. Do not discuss subjects' health conditions in public areas and with unauthorized research personnel; and do not leave research records uncovered and in public places.

4.7. **Access of Visiting Physicians/Investigators and non-AUB/AUBMC staff to medical records:** Refer to policy on Non-AUBMC Staff Participating in Clinical Research *(HRP-MUL-001)*.

4.8. **Access to medical records by Sponsors. Clinical Trial Monitors/Clinical Research Organizations (CTM/CRO):** Refer to policy on “Visits and Audits for Clinical Research by External Entities” *(HRP-MUL-004)*.

4.9. **Access to medical records by governmental or Regulatory agencies:** Refer to policy on “Visits and Audits for Clinical Research by External Entities” *(HRP-MUL-004)*.

4.10. **Access to Records of Deceased patients:**
   4.10.1. Accessing records of deceased patients for research purposes is not considered human subjects research and thus The IRB does not review and oversee such research studies. Accessing individually identifiable information from medical records of decedents for research purposes shall follow AUBMC rules and regulations.
   4.10.2. This access shall be regulated and authorized by AUBMC Administration.
4.11. **Physician Review of Records:**

4.11.1. AUB IRB approval is always required for research involving review of medical records, even if the medical records are of the physician’s own patients.

4.11.2. The privilege of accessing individually identifiable health information for clinical care does not translate into a right of using these records for research purposes. Patients in such instances are considered research human subjects and either an informed consent needs to be sought from them to permit the use of their medical records for research purposes; or a waiver of consent shall be granted by the IRB as per relevant regulations.

4.12. **Record Review Preparatory to Research:** Investigators sometimes desire to access existing records to identify potential research subjects in preparation for their research. This is permitted if the following conditions are met:

4.12.1. The use of individually identifiable health information is only to prepare a research protocol.

4.12.2. The work will not involve recording or removing health information from the medical records.

4.12.3. The requested health information is necessary for the purpose of the research.

4.12.4. The AUB IRB form (Request to access PHI-preparatory for research) to approve Preparatory review for research needs to be submitted for approval by the AUB IRB.

4.13. **Medical Records at AUBMC Clinics**

4.13.1. Medical records of all patients treated at any AUBMC clinic are the property of AUBMC and shall be subject to all aspects of this policy and all applicable procedures.

4.13.2. Medical records of all patients treated at any AUBMC clinic are considered an integral part of the patient’s medical record present at the medical center.

4.14. **Medical Records of Part-time Physicians:**

4.14.1. Medical records of patients treated by part-time faculty members are not considered AUBMC property and are generally kept in the custody of the part-time physicians and at their clinics.

4.14.2. Part-time physicians have faculty appointments at AUB and thus need to secure IRB approval for review of their own medical records for research purposes; as the institution is considered engaged in human subjects’ research in such instances.

5. **Responsibilities**

5.1. All investigators requesting access to AUBMC medical records for research purposes are responsible for complying with the policy and procedures set out in this document.

5.2. The Medical Records Administrator, Medical Records staff and if applicable, the responsible administrator for electronic health records (EHR) systems are responsible for ensuring that AUBMC medical records are not made available to investigators or their team members for research purposes except in accordance with the policy and procedures set out in this document.

5.3. Physicians and other clinical staff involved in the treatment and care of patients are responsible for ensuring that AUBMC medical records in their possession are not made
available to investigators for research, or used for research, except in accordance with the policy and procedures set out in this document.

5.4. The IRB shall refer PI’s who need patient information for research purposes to the AUBMC Decision Support unit after the application/protocol has been approved by the AUB-IRB.

5.5. AUBMC Decision Support Unit shall control and restrict the provision of patient information for research purposes per the recommendation and approval of the AUB-IRB.

[Remainder of this page left blank intentionally. Signatures follow on next page.]
6. Signature

<table>
<thead>
<tr>
<th>Reviewed and Concurred by</th>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chair, Institutional Review Board</td>
<td>Fuad Ziyadeh, MD</td>
<td>Signature</td>
<td>16/3/17</td>
</tr>
<tr>
<td>Director, Human Research</td>
<td>Ali Abu Alfa, MD</td>
<td>Signature</td>
<td>21/3/17</td>
</tr>
<tr>
<td>Protection Program and Associate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Center Director for Research Affairs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chief Quality and Compliance Officer</td>
<td>Petra Khoury, PharmD</td>
<td>Signature</td>
<td>27/3/17</td>
</tr>
<tr>
<td>Approved by</td>
<td>Name</td>
<td>Signature</td>
<td>Date</td>
</tr>
<tr>
<td>Chief of Staff</td>
<td>Samir Alam, MD</td>
<td>Signature</td>
<td>27/3/17</td>
</tr>
<tr>
<td>Medical Center Director and Chief Medical Officer</td>
<td>Hassan El Solh, MD</td>
<td>Signature</td>
<td>30/3/17</td>
</tr>
<tr>
<td>Deputy EVP/Dean</td>
<td>Ziyad Ghazzal, MD</td>
<td>Signature</td>
<td>3/3/17</td>
</tr>
</tbody>
</table>

7. References

7.1. IRB Manual
7.2. Confidentiality, Security, and Release of Patient Information (MOI-MUL-002)
7.3. Visits and Audits for Clinical Research by External Entities (HRP-MUL-004)

8. Modifications

8.1. Modifications made to the 2nd edition of this policy: Addition of the Role of the AUBMC Decision Support Unit in controlling the provision of patient information for research purposes.