1. SCOPE / DOMAIN OF APPLICATION:

To describe the procedure for approval, access of information, and contacting of patients for participation in research at MLH- UMC

2. PURPOSE:

It is mandatory for all Physicians/ Residents/ Students of Mount Lebanon Hospital - University Medical Center (MLH-UMC) to follow the set guidelines prior to contacting patients for any project or research.

3. DEFINITION(S) AND ABBREVIATION(S):

- HIS: Hospital Information System
- ICD-10: International Classification of Diseases
- IT: Information Technology
- LIS: Laboratory Information System
- MLH- UMC: Mount Lebanon Hospital – University Medical Center
- PACS: Picture Archiving and Communication System
- SMS: Short Message Service

4. POLICY(IES):

MA-PO-59:
Human subjects' research within Mount Lebanon Hospital not is guided by regulations and by the executive committee. The executive committee:

- Appoints a responsible for maintaining the development of and compliance with all human subjects research policies and procedures
- Assumes responsibility for patient protection irrespective of the research
- Recognizes and establishes mechanisms for compliance with all regulatory and professional requirements related to research
- Ensures that there is a source of indemnity insurance to adequately compensate patients participating in clinical research who experience and adverse event

Human subject research within Mount Lebanon Hospital is not conducted to inpatients but only outpatients; therefore, admission and/or transfer criteria to a specialized ward due to research and/or another specialized program is not required.

5. PROCEDURE:

5.1. Process Flow:

- Follow guidelines of Human Subjects Research MA-P-18
- Fill Permission to Access Medical/ Confidential Information MC-F-134
- Submit permission MC-F-134 to Ethics Committee
- Ethics Committee to send scanned copy to IT department with specified start and end dates of project
- IT to confirm reply by mail with the actions taken (SMS + extension + data extracted)
- Ethics Committee to communicate with research group to start

MC-F-134 will enable:

- An SMS to be sent to patients prior to calling them (prepared template in bullet 5.5)
- An internal extension to be created in order to contact patients from a landline within the hospital

- The extension will be valid/unlocked at the start date and locked at the end date (example: 2 months of data gathering)

5.2. Call timings:

Monday to Friday: 10 AM to 7 PM
Saturday: 10 AM to 1 PM
Sunday/ Holidays: NO CALLS

5.3. Permission to Access Medical / Confidential Information (MC-F-134):

All Physicians/ Residents/ Students are requested to complete the **Permission to Access Medical/ Confidential Information** and submit it a minimum of 15 days prior to the start date. This will ensure that all approvals have been received.

5.4. Request for patient data:

here are several information software available to extract data:
- Laserfiche
- PACS
- HIS
- LIS
- Hard copy of the medical record

The kind/amount/and details of information can include the following items listed below:
Case #, Department, File Number, First Name, Middle Name, Family Name, Gender, Date of Birth, Entry Date, Exit Date, Doctor Name, Diagnosis Description, ICD-10.

5.5. SMS Template:

An SMS template; with the below format; will be sent out to each participant prior to calling them:
Invitation to participate in a research study by Dr _____,
Subject: _____ Expected call on_____
Thank you for your cooperation.

5.6. Guidelines while communicating with patients:

When speaking to patients or their family members, make sure to:
- Introduce yourself
- Make sure you are speaking to the patient
- Always remain polite, no matter the attitude received from the patient
- Answer all questions asked
- Reveal all aims of the project
- Do not exceed the time limit specified
- Abide by the Dress code procedure MA-P-23

5.7. Notice for physical interviews:

All Physicians/ Residents/ Students must submit a patient informed consent for telephone survey or informal interview to be used for the purpose of their study.
https://www.who.int/groups/research-ethics-review-committee/guidelines-on-submitting-research-proposals-for-ethics-review/templates-for-informed-consent-forms

ENGLISH:
Good morning/afternoon,
Am I speaking to Patient Full Name?
This is Dr. Full Name from the department of *department name* at Mount Lebanon Hospital.
I am contacting you to participate in the study of "……"
May I take a minute to explain?

If No: ok thank you for your time, have a nice day Patient Full Name

If Yes: If you agree to participate:
- 5 mins phone interview
- confidential
- Used only for the purpose of the study
- Would you be willing to participate?

If No: Ok thank you for your time, have a nice day Patient Full Name

If Yes: Your participation is highly appreciated I will be explaining some conditions before starting:
- THE PARTICIPATION IS VOLUNTARY
- You will help others to better understand …….
- There are no FEES ASSOCIATED
- There is no penalty if you refuse to participate
- Your participation will not affect the level of care from your Doctor
- Your participation will not affect your relationship with Mount Lebanon Hospital University Medical Center
- Please feel free to ask any question
- Feel free to end the survey at any time
- The results will be audited by management by following standards of privacy and confidentiality

Were all the points mentioned clear or would you like to know more?
Yes/No
We will begin the survey Patient Full Name

End: Thank you for your time and for trusting MLH-UMC, have a nice day Patient Full Name

Date of Interview:
Patient Name:
Interviewer Signature:

ARABIC:

مرحباً،
هل أتكلّم مع الاسم الكامل للمريض؟
أنا الدكتور الاسم الكامل من قسم اسم القسم في مستشفى جبل لبنان الجامعي
أنا أتّصل بك للمشاركة في دراسة :
هل يمكنني أخذ دقيقة من وقتك؟

اذا كانت الاجابة كلا : شكراً لوقتك الاسم الكامل للمريض، أتمنى لك يوماً سعيداً

اذا كانت الاجابة نعم : في حال وافقت على المشاركة :
- مقابلة هاتفية لمدّة ٥ دقائق
- مؤتمن

- تستخدم فقط بهدف الدراسة
- هل ترغب في المشاركة؟

في حال كانت الإجابة كلا : شكراً لوقتك الاسم الكامل للمريض، أتمنى لك يوماً سعيداً

في حال كانت الإجابة نعم : أقدّر كثيراً مشاركتك معنا، سوف أطلعك عن بعض الشروط :
-المشاركة طوعيّة
- سوف تساعد الآخرين على فهم ...
- لا توجد رسوم
-لا توجد عقوبة إذا رفضت المشاركة
- لن تؤثر مشاركتك على علاقتك بمستشفى جبل لبنان الجامعي
- لا تتردّد في طرح أي سؤال
- لا تتردّد في إنهاء الاستطلاع في أي وقت
- سوف يتم مراجعة النتائج من قبل الإدارة باتباع معايير الخصوصيّة

هل كل النقاط المذكورة واضحة ؟ أو ترغب بمعرفة المزيد؟
نعم / كلا

سوف نبدأ بالأسئلة
النهاية : شكراً اسم المريض الكامل على وقتك و ثقتك بمستشفى جبل لبنان الجامعي، أتمنى لك يوماً سعيداً

تاريخ المقابلة:
اسم المريض:
توقيع المحاور:

FRENCH:

Bonjour,
Nom complet du patient? Pouvez-vous me mettre en ligne/contact avec Nom complet du patient
Je m'appelle Dr. Nom complet du département de nom du département à l'Hôpital Mont-Liban.
Je vous contacte pour participer à l'étude suivante: "……"
Puis-je prendre une minute de votre temps pour vous expliquer le déroulement?

Si non: merci pour votre temps, passez une bonne journée Nom complet du patient

Si oui: Votre participation à cette enquête:
- Durera 5 minutes
- Confidentiel
- Uniquement utilisée dans le cadre de cette étude
- Etes-vous intéressé de participer?

Si non: ok merci pour votre temps, passez une bonne journée Nom complet du patient

Si oui: Votre participation est très appréciée, je vais énoncer les conditions de votre participation avant de commencer le questionnaire:
- La participation est volontaire
- Elle contribuera au bien de la société
- Il n'y a pas de frais associés
- Il n'y a pas de conséquence liée à votre refus de participer
- Votre participation n'affectera pas les soins reçus par votre médecin ou le corps médical
- Votre participation n'affectera pas votre relation avec l'hôpital
- N'hésitez pas à poser toutes questions

- Vous pouvez interrompre le questionnaire à n'importe quel moment
- Les résultats seront audités par l'administration sous respect des standards de respect de la privacité

Pouvez-vous confirmer que les conditions énoncées sont claires, avez-vous besoin de renseignements supplémentaires?

Oui/Non

Nous allons commencer l'enquête
Fin: Merci de nous accorder votre temps, Passez une bonne journée Nom complet du patient

Date de l'entretien:
Nom du patient:
Signature de l'interlocuteur:

5.8. Internal telephone:

For IT purpose: all extensions for resident projects to have similar specifications:
Naming: Res + First name + Last name
Extension: Starting with 79 followed by three different digits example: 79153

6. ANNEXE(S):

MC-F-134: Permission to Access Medical/Confidential information

7. REFERENCE DOCUMENT(S):

MA-P-18: Human Subjects Research
MA-P-23: Dress Code Fellows, Residents, Hospitalists and Students