To the Research Community:

As you know, Montefiore recently began using Epic. To ensure continuity of care for our subjects, the IRB requires that a copy of Epic Information Sheet be provided to all subjects who come in for a study-related visit AND subjects were enrolled with a consent document approved prior to March 2015. The FAQ below explains how it is to be used. If you have any additional questions, please feel free to contact the Epic Research Manager at 914-922-6030 or the IRB at 718-430-2237 or irb@einstein.yu.edu.

English and Spanish versions of the Epic Information Sheet are provided at the end of this document.
Frequently Asked Questions (FAQ)

Question 1: How do I know if this applies to my study?

Answer 1: The memo needs to be signed by your study participants at their next study visit if your study involves the enrollment/treatment of subjects at Montefiore and you enrolled subjects with a consent form that lacks the statement, “Medical information collected during the research, such as test results, may be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.” or the bullet “clinicians and staff at Montefiore who review your records for your care” in the Confidentiality section. In general, new consent forms approved by the IRB after March, 2015 contain this language, and the information sheet does not need to be provided to subjects who signed a consent form containing this language.

The two templates look like:

December 2014 Template

Confidentiality
We will keep your information confidential, however, a risk of taking part in this study is that your confidential information might be shared accidentally with someone who is not on the study team and is not supposed to see or know about your information. This is very unlikely, because the study team takes confidentiality of your information seriously. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a locked file cabinet and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information [if relevant: and specimens] will be kept as long as they are useful for this research.

The only people who can see your research records are:
- the research team and staff who work with them
- clinicians and staff at Montefiore who review your records for your care
- the organization that funded the research
- organizations and institutions involved in this research: [LIST]
- groups that review research (the Einstein IRB, and the Office for Human Research Protections, [if relevant: and the US Food and Drug Administration])

These people who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.
April 2016 Template

Confidentiality

We will keep your information confidential. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a secure manner and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information [if relevant] and specimens] will be kept as long as they are useful for this research.

Medical information collected during the research, such as test results, may be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.

The only people who can see your research records are:
- the research team and staff who work with them
- the organization that funded the research
- organizations and institutions involved in this research: [LIST]
- groups that review research (the Einstein IRB, and the Office for Human Research Protections, [if relevant: and the US Food and Drug Administration])

These people who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

Question 2: Who needs to sign the information sheet?
Answer 2: Only study participants who have an upcoming visit. Study participants who have completed all study visits do not need to be contacted.

Question 3: For which studies do study participants NOT have to sign this form?
Answer 3: Study participants do NOT have to sign this form if the study does not involve any study-related tests or procedures at Montefiore. This includes blood draws. Patients that will have study related blood tests, echo cardiograms, and radiology procedures (e.g. x-rays, MRIs, CT scans and ultrasound) need to sign this form even if these procedures are standard of care.

Question 4: What's the procedure for enrolling new study subjects?
Answer 4: If your consent form(s) lack either of the required statements in the Confidentiality section (see Question 1), new subjects must sign the information sheet in addition to the consent form. (Note: You may submit an amendment to the IRB to add the statement to your consent(s) to avoid the need for the extra form going forward.)

Question 5: What information should I add to my revised consent document?
Answer 5: You should add the following statement to the Confidentiality section of the consent document:

English:
Medical information collected during the research, such as test results, may be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.

Spanish:
La información médica que se recoja durante la investigación, como los resultados de pruebas, se puede ingresar a su expediente médico electrónico de Montefiore y estará disponible para los médicos y otro personal de Montefiore que le proporcionan atención médica.

Question 6: What happens if a study participant refuses to sign this form?
Answer 6: You should make a note in the study records that you have given them this information. Refusing to sign this form does not mean the study participant must withdraw from the study. However, if the study participant wishes to withdraw the study, you should withdraw them.

Question 7: Does this apply to consent documents approved by other IRBs such as BRANY?
Answer 7: Yes. BRANY will be sending out guidance for consent documents it has approved. For studies approved by other outside IRBs, please submit an amendment to them updating your consent documents to include the required language in the Confidentiality section (Medical information collected during the research, such as test results, may be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.), and use the Information Sheet in the interim.

Question 8: What if my subject only speaks Spanish?
Answer 8: We have provided a Spanish translation of the memo at the end of this document.

Question 9: What if we would like to adapt our current Spanish translation of the consent document?
Answer 9: Add the following paragraph to the Confidentiality section of your translated consent document: La información médica que se recoja durante la investigación, como los resultados de pruebas, se puede ingresar a su expediente médico electrónico de Montefiore y estará disponible para los médicos y otro personal de Montefiore que le proporcionan atención médica.

Question 10: What if our study is enrolling children?
Answer 10: For participants who are under the age of 18, the participant’s parent or guardian should sign on the child’s behalf (and include his/her name in the “Signature of participant” box).

Question 11: When does this take effect?
Answer 11: This became required June 1, 2016.
New Information about your Medical Record

Montefiore recently adopted a new electronic medical record system, called Epic, and its related systems. Going forward, your study-related information (visits, test results, etc.) will be entered into Epic. This will allow your physician and other members of your care team to see the study-related information in your record, which may be useful in planning your care.

If you have any questions about this, you may discuss them with the researchers, the Epic Research Manager at 914-922-6030, or the Institutional Review Board (IRB) that oversees this research at 718-430-2253.

IRB #:______________

Acknowledgement of Receipt

I have read the statement above and have been given a copy of this memo.

Printed name of participant  Signature of participant*  Date

Printed name of researcher  Signature of researcher  Date

*For participants who are under the age of 18, the participant’s parent or guardian should sign (and include his/her name in the “Signature of participant” box).
Nueva Información sobre su Expediente Médico

Montefiore ha empezado a usar recientemente un nuevo sistema electrónico de registros médicos, llamado Epic, y los sistemas relacionados con este. En adelante, su información relacionada con estudios (como, visitas, resultados de exámenes, etc.) se ingresarán a Epic. Esto permitirá que los médicos y otros miembros de su equipo de atención médica vean la información relacionada con estudios en su expediente, la que se puede usar en la planificación de su atención médica.

Si tiene alguna pregunta sobre esto, puede comunicarse con los investigadores, el Director de Investigaciones de Epic al 914-922-6030, o la Junta de Revisión Institucional (Institutional Review Board, IRB) que supervisa esta investigación al 718-430-2253.

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<th>N.º de la IRB : ________________</th>
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**Acuse de Recibo**

He leído el comunicado que se menciona anteriormente y he recibido una copia de este memorando.

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<thead>
<tr>
<th>Nombre en letra de imprenta del participante</th>
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<tr>
<th>Nombre en letra de imprenta del investigador</th>
<th>Firma del investigador</th>
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*Si el participante tiene menos de 18 años de edad, la madre/el padre o el tutor del participante deberá firmar (e incluir su nombre) en la parte «Firma del participante».*