Electronic Medical Records and Research Results

The IRB has recently added language to the informed consent form template to inform subjects about the potential for research results to appear in their electronic medical record maintained by the University of Pennsylvania Health System (“UPHS”). This language is required for all research that involves UPHS resources (e.g. a laboratory or imaging services) or involves a research procedure that generates test results that may be placed in a subject’s electronic medical record. The purpose of this document is to provide guidance to the research community to help explain the meaning of this language to research subjects.

An explanation of the required language is outlined below. Responses to frequently asked questions about electronic medical records and research results are also included in this guidance document.

I. Required Language:

Electronic Medical Records and Research Results

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any results of procedures performed as part of this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Results of research procedures performed as part of your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).
II. Explanation of the required language by paragraph

Paragraph 1:
*An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.*

**Explanation:** The purpose of the first two sentences is to provide a lay description of what an electronic medical record is and how it is different from a paper medical record.

Paragraph 2:
*If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR.*

**Explanation:** This paragraph is meant to target the individual who has previously received care within UPHS and who has an existing EMR. When consenting a subject, a good approach to addressing this section may be asking the potential subject whether he/she has ever received care within UPHS previously. This will help you to identify and inform the subject whether this portion of the required language will apply to the individual subject or if **paragraph III**, described below, will be more relevant. If the subject is not sure whether he/she has previously received care within UPHS, you should discuss both sections.

This paragraph contains a few critical components:
1. The definition of UPHS includes both outpatient and inpatient services within the health system. This is meant to make clear to the subject that even if they have only visited a UPHS outpatient facility, such as a diagnostic testing site for a radiology (imaging) study, they will have an existing EMR.
2. A statement informing subjects that results of research procedures may be placed in the existing EMR. Please note the following:
   a. The examples of tests outlined are those that have the likelihood of being added to the EMR. Surveys or telephone questionnaires are not likely to be added to a subject’s EMR so they are not included as potential examples.
   b. The language says “may” be placed in the medical record because there is no guarantee that results will be included or can be kept out. A few important things to remember related to this:
      i. Test results for research procedures using UPHS services (e.g. a UPHS lab or imaging facility) WILL be included in the subject’s medical record.
      ii. Tests results from tests performed at service centers (e.g. a research lab within the School of Medicine or an outside commercial lab) may also be included. Although these results are not required to be included in the EMR for billing purposes, they have the potential to be included.
Paragraph III:
If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any results of procedures performed as part of this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Results of research procedures performed as part of your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Explanation:
This paragraph is meant to target the individual who has never received care within UPHS and who does not have an existing EMR within the UPHS system. When consenting a subject, a good approach to addressing this paragraph may be asking the potential subject whether he/she has ever received care within UPHS previously. This will help you to identify and inform the subject whether this portion of the required language will apply to the individual subject.

This paragraph contains one critical component in addition to the key components outlined in Paragraph II above:

1. This paragraph informs the subject that one requirement of participating in a research study at Penn that utilizes UPHS services is the creation of an EMR to track, and often schedule, the services used for that subject.
   a. All subjects who participate in a study using UPHS services who do not have an existing EMR within UPHS are required to have an EMR created for them for research billing purposes. Having this record will help facilitate appropriate billing according to the billing plan agreed upon for your study.
   b. The creation of this EMR requires that the subject be asked the required “registration” questions in order for the study team to be able to create the record. The information that must be collected is similar to information that would be collected at the time a new patient chart is created the first time a patient visits a medical facility.
      iii. Please note: This may include more information than you would typically require for the purpose of your research study.
      iv. The specific information that you will need to collect for creation of the EMR must be included in the combined informed consent form and HIPAA Authorization Form in the section titled What Information about Me Will Be Collected?”

Paragraph IV:
Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

Explanation:
This paragraph is meant to inform the subject of the potential for others outside of the study team to view research results that are included in the EMR. This section informs the subject of the following:

1. Research results included in the EMR could be seen by others within the UPHS system who have appropriate access (for example the subject’s PCP).
2. Research results included in the EMR will be viewed by and may be disclosed to third parties who are granted appropriate access to the EMR (e.g. a public health agency).
Frequently Asked Questions

1. What do you mean when you say Electronic Medical Record?

The electronic medical record (“EMR”) refers to all potential sources of electronic information in which an individual’s record of care may be captured. This includes but is not limited to EPIC, Medview, eWebHealth, Sunrise, Cerner, GEcentricity and other diagnostic testing systems.

2. My study does not use UPHS services. Why do I have to include this language in my consent form?

Even if your study uses an outside service (e.g. a commercial lab) there is a potential that results from these tests may feed back into the EMR for an individual. This could occur because of links established for billing purposes or may occur simply because an individual scans the record and inputs it into the system. Since there can be no guarantee that research results will not be included in a subject’s EMR, this language is required to inform subjects of this potential.

3. Can certain research results remain outside of the EMR?

Although there are mechanisms in place to restrict the information that may be included in the EMR, these mechanisms cannot be guaranteed as results can be placed in the EMR by a simple action such as a fax between investigators for consultation on a test result. For this reason, subjects must be informed of the potential that research results may be included in the EMR. Furthermore, once placed in the record, clinicians may subsequently incorporate those results (even normal results) into future clinical decision making.

4. What if a subject asks not to have the research results included in their EMR?

The study team should inform the subject that unfortunately, this cannot be guaranteed and agreeing to participate in this study means that the subject is willing to participate knowing that this may occur.

For more information please contact Megan Kasimatis Singleton, Associate Director of the IRB at mkasimat@upenn.edu or 215-746-6275.