Penn | Human Research Protections Program
University of Pennsylvania

21st Century Cures Act and Electronic Medical Records Access

As a result of the 21st Century Cures Act, Penn Medicine is required to allow patients increased access to their electronic medical record.

IMPACT ON RESEARCH
With the Cures Act, by default, *research-related information** that is placed in the participant's EMR will now be available within 10 days via MyPennMedicine (MPM), Penn Medicine's patient portal. **This goes into effect on April 2, 2021.**

Research-related information refers to research data or information that may be contained in research notes, clinical progress notes, physician orders, test results, etc.

Delayed Release and Suppression of Research Related Information
The law allows for suppressing research-related information within the medical record. However, exceptions are very restrictive (e.g., risk of immediate physical harm to self or immediate harm to care team). *The possibility of mental harm, and risk of proxy viewing for pediatric population does not meet the threshold of suppression.*

The law also allows for delayed release of research-related information within the medical record.

If research-related information is *suppressed* OR *released in a delayed manner*:
- The participant must be informed within the consent form that certain results may not be released to them or released in a delayed manner.
  - Please see the section "Electronic Medical Record and Release of Study Related Information" within the biomedical informed consent template.
- Reasons for suppression or delayed release should be outlined within the study protocol.

This applies to new and existing research protocols that are built within the EMR.

For guidance on how to delay or suppress results within the EMR, please contact the Office of Clinical Research.

Valid reasons for not returning or for delaying release of research related information within the EMR:
- Release could lead to unblinding and bias the study
- The meaning and clinical significance are not known;
- The information lacks validity or actionability
- There will be no clinical read of results
- Others as approved on a case by case basis by the IRB

Amendments to Existing Approved Research
An amendment should be submitted for existing protocols that are built within the EMR to revise consent forms (and as applicable, protocols), *if there is suppression or delayed release of research-related information in the EMR, that was not previously described in the consent*.

If there will be no delays, nor suppression of research-related information, an amendment is not required.

If there are no significant changes to the informed consent document, re-consent is not required. In essence, re-consent is not required unless what is being released has changed.