

Consent Forms: Inclusion in Medical Records

Overview:

In response to a Centers for Medicare & Medicaid Services (CMS) directive, UPMC now requires that all signed documents uploaded into a medical record include the date and the time each signature was obtained. For medical researchers, this means that **IF** the research consent form is going to be uploaded into the UPMC medical record system, **EACH** signature on the research consent form must include the date and time the person signed the document.

Description:

If the research consent form is going to be uploaded into the medical record, there are two approaches that can be taken to ensure that the time of signature is captured:

1. Include a line for “time” on the IRB-approved consent form
 - The IRB must approve the consent form with the “time” line included
 - Failure to include the time with all signatures will require a report of non-compliance to the IRB and UPMC
2. Do not include a line for “time” but instead have all signatories write in the time on the IRB-approved consent form
 - IRB approval of this process is not required
 - Failure to include the time with all signatures requires a report of non-compliance to UPMC but not to the IRB

As an alternative to including the consent form in the medical record, investigators may include a note that the person is participating in a research study along with a brief summary of the study that includes relevant contact information as well as information about the drug/device and possible serious risks associated with study participation.

Considerations:

There is no requirement – either from the University IRB, CMS, JCAHO or UPMC – that research consents be included in the medical records. However, certain units (e.g., CTCRCs) may require or strongly recommend that research consent forms be included in the records.

Consent Document:

The following statement should be included when the consent form will become a part of the medical record: ‘A signed copy of this consent form will be included in your medical record’.

Additional Information:

Office of Sponsored Programs and Research Support (OSPARS)

OSPARS@upmc.edu or (412) 647-4461