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., CTRCs) 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