

In This Issue

- Report on Informed Consent Documentation Initiative

Quick Links

- [University Hospitals](#)
- [Center For Clinical Research](#)
- [Office of Research Compliance](#)
- [UHCMC IRB](#)
- [UHCMC Grants and Contracts](#)
- [William T Dahms Clinical Research Unit](#)



Questions, Comments, Suggestion?

If you have questions, comments or have a suggestion about how we can improve our human research protection program (HRPP) at UHCMC, send an email to: clinicalresearch@uhhs.com or contact Carol Fedor, Clinical Research Manager at (216) 844-5524

Contact Us

Office of Research Compliance
Lakeside 1400
11100 Euclid Avenue
Cleveland, Ohio 44106
216.844.5576

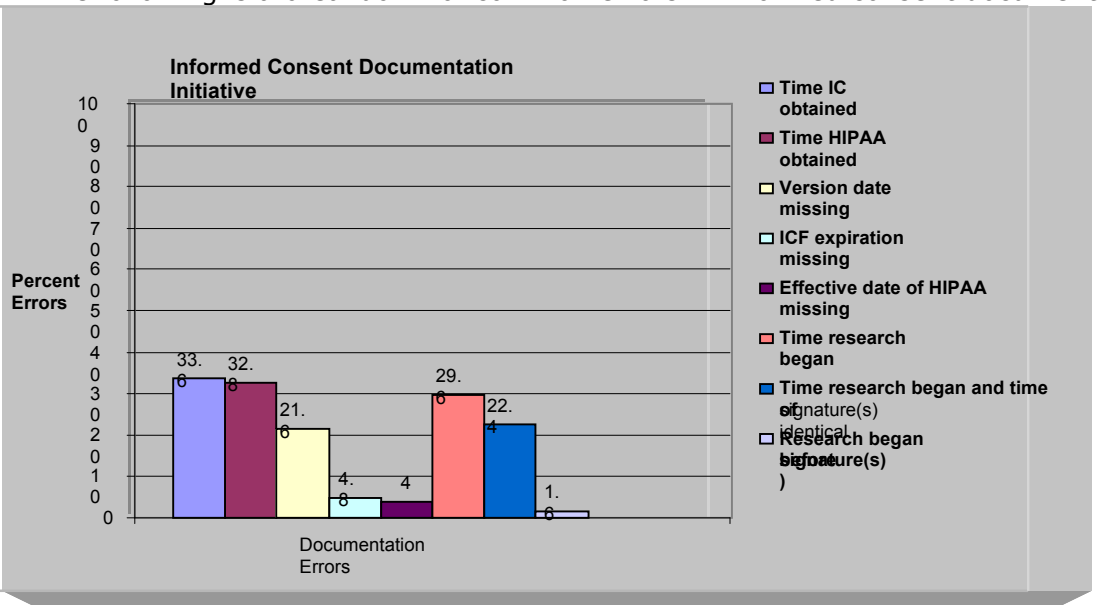
E-mail us!

Report on UHCMC Informed Consent Documentation Initiative

Documentation of the Informed Consent process is fundamental to the protection of human research participants (21 CFR 50.27(b)). The Center for Clinical Research and Technology (CCRT) introduced an Informed Consent Documentation Initiative (ICDI), earlier this year, to promote consistency with documenting the informed consent process.

The first step was to develop and pilot a template checklist to be used by UHCMC research personnel to measure consistency of documentation and compliance with the required components of the informed consent process. A number of departments at UHCMC participated in the pilot by reviewing the research records to complete the Informed Consent Documentation (ICD) template checklist.

The following is a breakdown of common errors in informed consent documentation:



Based on the information collected during this pilot test, the CCRT has come up with this list of "best practice" tips to ensure appropriate documentation of the research informed consent process:

- Informed Consent must always be presented and signed **before** any research activities begin.
- "Research activities" includes not only data collection, but also all screening procedures.
- Always use the **current IRB approved version** of the Informed Consent form. Informed Consent forms that expire, per the IRB approval stamp, before written consent is obtained are considered invalid.
- Always include documentation of the time at which consent and research activities occur.

The ORC is currently finalizing the ICD template and will require use with all UH research projects to streamline documentation requirements and improve compliance. This template will also be incorporated as part of the UH Electronic Medical Record project. More information about the official rollout of the ICD template will follow in the coming months.