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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

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Informed Consent Requirements for UHCMC Medical Records

Under Federal regulations and Joint Commission standards, the Office of Research Compliance and Education of University Hospitals Case Medical Center (UHCMC) reviews compliance with informed consent documentation in the medical record. The purpose of the audit is to ensure that the informed consent document contains the elements outlined in the code of federal regulations (§50.25) and that a fully executed copy of the informed consent document is present in the UHCMC medical record. The **fully executed copy** of the informed consent document must include all required signatures including the research participant and legally authorized representative (as applicable), individual obtaining consent and the Principal Investigator's signature. As the Principal Investigator is allowed a 30-day period to sign the consent form, researchers must ensure that the copy being forwarded to the medical record includes all required signatures. The research participant's medical records are selected at random for review by the Office of Research Compliance, and results are reported to the Principal Investigator on a quarterly basis.

Research Ethics: Case Study

The Center for Clinical Research and Technology (CCRT) hosted a Research Ethics Practicum, earlier this year, in collaboration with the Department of Bioethics at Case Western Reserve University. During the 7-week rotation, three graduate students participated in the day-to-day operations of our research administration office. At the conclusion of their experience, the students developed the following Research Ethics Case Study as a prototype for future newsletters and to serve as an educational exercise for the research community.

Case Study #1: Protocol Continuing Review and HSP Certification

In preparation for the upcoming continuing review of his protocol, Principal Investigator (PI) Smith begins reviewing the research regulatory records. PI Smith notes that most of his staff received their CREC certification. However, several new staff members have been on the research protocol for only a few months and have not completed the Human Subjects Protections (HSP) certification requirement. The new staff members obtain consent from research participants, since PI Smith has explained the informed consent process to each of them personally. The non-certified staff are permitted to continue to consent participants and reminded to complete the CITI courses "when they have time". During a review of the adverse events that have occurred since the last continuing review, PI Smith realizes that 3 months ago, a research participant developed severe migraines and internal bleeding that required hospitalization. The serious adverse event had not been immediately reported to the IRB since hemorrhaging was noted as a risk on the informed consent document and the subject quickly recovered. PI Smith plans to include the adverse event in the continuing review summary. At last, PI Smith is ready to complete the required forms for the continuing review. At this point, there is only one month until the protocol expires so PI Smith uses the continuing review forms from last year to save time, only making changes where necessary. What are some of the concerns that arise in PI Smith's protocol?

Key Concerns:

- All personnel who obtain consent are required to complete the Human Subjects Protections certification prior to consenting patients. The CCRT further recommends that all research personnel that interact with research participants are also certified.
- All serious, study related adverse events, whether expected or unexpected, must be reported to the IRB within 14 calendar days of the event. Investigators can visit the website or contact the CCRT staff regarding reporting requirements for serious adverse events, study related events, expected events, etc.
- Contact the CCRT staff or check the website to verify that submission forms and templates are the current versions. A part of human research protections is keeping abreast with the changes and improvements for the human research protection program.

The UHCMC IRB recommends that protocol renewals be submitted **at least six weeks prior to expiration** to ensure sufficient time for IRB review.