Memo-to-File: from the EQuIP Office

Consent is not a document signed and dated before a subject is enrolled in a study; *rather* it is an on-going process documented throughout a subject's participation in a study.

The following are a few ***Best Practices*** identified during recent EQuIP **Study Reviews***:

☑ **Identifying the need for and documenting re-consent**

When the IRB approves an amendment that involves new information which may affect the subject's willingness to continue participation in a study, the investigator is required to inform the subject/family before the next study visit/procedure as part of the on-going consent process. Like any other study procedure, the research team should document this in the subject's study record (e.g. Memo-to-file, study visit checklist). Depending on the type of research and information, the IRB may require that active subjects are re-consented with the amended consent form prior to further study participation.

☑ **Identifying and promptly consenting subjects who turn 18 while still enrolled in ongoing research**

Unless the requirement has been explicitly waived by the IRB, any minor subject enrolled via parental permission and assent that subsequently turns 18 while enrolled in a research study must be consented consent as an adult prior to continued study participation. Research where this typically occurs would be that involving longitudinal follow up, prospective review of medical records, or ongoing sharing of samples via a repository. Research teams should develop and implement a method to track and identify in real-time minor subjects who turn 18 during a study. E.g. add a field which calculates age to an enrollment log or database and alerts research team when a subject turns 18 in relation to subsequent study visits/follow-up contacts. See related CCI/IRB Guidance.

* A confidential, full or partial review of on-going studies to ensure compliance with applicable regulations and policies and to evaluate study conduct, organization, record-keeping and documentation. The EQuIP office aims to help investigators implement tools and strategies to improve identified problem areas. Reviews may be voluntarily requested by PI/staff (eg to ensure compliance, during staff changes, to prepare for an external audit).

Visit the EQuIP website for more information and resource or call Eunice Newbert or Susie Corl at the EQuIP