Summary of Informed Consent (IC) Audits

Conducted on non-English speaking patients enrolled on 01C0129 and 04C0165 from 1/1/2020 through 7/31/2020*

48 informed consents were reviewed

- 9 short form consent processes
- 36 Spanish translated long form used
- 4 minor patients (one was non-English speaking)

Overall Findings

- 36 (75%) had issues with informed consent or CRIS documentation
  - 7 of these had issues that required expeditated reporting to the IRB

	Details
Issues that required expedited reporting to the IRB	• During short form consent process, the non-English speaking patient signed both the short form and the long English consent document • During short form consent process, a witness did not sign the short form or long form • When using the translated Spanish long form, the Spanish speaking patient signed the translated long form and the investigator signed the English consent form • Spanish speaking minor patient signed the English assent form • Investigator obtaining consent was not listed on the Key Study Personnel form (2 instances) • NIH Administrative section identifying the interpreter used not completed for three non-English speaking patients
Issues with informed consent document	• When informed consent obtained via telephone and signed consent was not returned by the patient the same day, investigator "backdated" their signature to the date of the telephone conversation • Witness signature not needed when the fully translated Spanish form was used • Protocol information not completed in the header of the short form • Incorrect version of the short form used
Issues with CRIS documentation	• Note did not indicate interpreter used • Note did not indicate that assent was obtained (or document a reason why assent was not obtained as required per protocol) • Note did not indicate that LAR/parental consent obtained for minor patient • Note entered 8 months after consent was signed • Note contained incorrect information (wrong protocol number) • Note contained conflicting information (different dates within note) • Note indicated assent was used when an adult patient signed the consent

*Patients enrolled in April were previously reviewed in another audit. For protocol 04C0165, several English-speaking minor patients were selected to review the assent process and documentation.