CHAPTER 3. INFORMED CONSENT

3.1 Informed Consent Document

The Data Coordinating Center (DCC) will provide a protocol-specific informed consent template for all the Childhood Liver Disease Research and Education Network (ChiLDREN) study sites. Each ChiLDREN study site will customize the template and receive approval from their study site's human subject protection committee.

The written informed consent should be brief and written in plain language so that a subject's parent(s) or legal guardian(s) who has not graduated from high school can understand the contents. An investigator, subject or subject's parent(s) or legal guardian(s) and witness should each sign and date the informed consent documents. The subject's parent(s) or legal guardian(s) should receive a copy of the signed and dated informed consent form. The study site must maintain a signed copy of the informed consent document for each subject in the study. Good Clinical Practice (GCP) guidelines require that source documents should indicate that the informed consent form was signed, along with the date of signing. No collection of data related to the study or to procedures will be done prior to completion of the informed consenting process.

3.2 Obtaining Informed Consent

For the START Trial, informed consent must be obtained within 72 hours from when the portoenterostomy was performed. Families of potential subjects may be approached prior to the portoenterostomy. Written informed consent will be obtained either after a decision is made by the attending physician at the ChiLDREN study site that the infant will undergo an exploratory laparotomy with possible portoenterostomy, or within 72 hours after portoenterostomy.

The study will be discussed in detail by the physician and Clinical Research Coordinator (CRC); and the informed consent reviewed.

The informed consent will include:

- Study purpose.
- Description of procedures.
- Risks and benefits.
- Alternative treatments.
- Costs.
- Compensation.
- Issues of confidentiality.

As part of the informed consent, the subject's parent(s) or legal guardian(s) will be informed of potential side effects of corticosteroids, as well as of potential adverse consequences of the sudden discontinuation of high doses of corticosteroids (after use for more than 2 weeks). Signed and dated informed consents will be obtained from the subject's parent(s) or legal guardian(s). The consent should be signed and dated by the investigator or designee (designee must be documented on the delegation log). Assent will not be sought from study subjects because they will be infants at entry into this study.

Failure to give informed consent renders the subject ineligible for the study. No research testing /exams or study medication will occur before informed consent has been obtained.

3.3 Re-Consent

If there is a change in any of the study procedures that may affect the subject, the informed consent document must be revised and again approved by the Institutional Review Board (IRB). Any subjects enrolled in the study prior to such changes may be required to sign an amended consent form, dependent on local IRB requirements.

3.4 Health Insurance Portability & Accountability Act (HIPAA) Compliance

At most study sites, a HIPAA form is presented to a potential subject for signature, in addition to the informed consent form, unless the necessary assurances are incorporated into the informed consent form. The HIPAA form describes subject and data confidentiality associated with the study.

3.5 Non-English-Speaking Subjects

Many IRB's mandate whether a translated consent document is needed to obtain consent from non-English speaking subjects or whether a translator can be used to obtain consent. Each study site must conform to their local requirements. With respect to completing Case Report Forms (CRFs), each study site should attempt to do their best to avoid errors as a result of translation.

3.5.1 Other issues related to translators

- A Human Protection certificate is not needed for the translator because the translator is only translating what the health care professional is stating; they do not provide patient care or collect data.
- Translation of any instructions is the responsibility of the study site and should be handled in the same manner as for non-research subjects.

- All expenses and budget issues related to using translators are study site-specific and should be discussed with the Principal Investigator (PI).

  NOTE: Translator issues are study-site specific; they are the responsibility of the study site / PI.