



**Instructions for
Data Collection
May 2004**

Study Toward Evidence-based Pediatric Surgery

NECSteps data are collected on paper forms for submission to the Lead Site at Yale University School of Medicine (SOM). Electronic data entry and database management will also take place at Yale SOM, however, responsibilities for data analysis will remain a joint project of Larry Moss, Bonnie Silverman and the Data Analysis Team at Stanford University.

The data forms and the process for collecting and submitting data are described below.

Please keep copies of the completed forms under lock and key at your site. Mail the originals to:

**Bonnie Lang Silverman, PhD
Research Coordinator
Children's Surgery Research Center
Yale University School of Medicine
330 Cedar Street, FMB 207
PO Box 208062
New Haven, CT 06520-8062**

Please notify Bonnie via an email when sending data: bonnie.silverman@yale.edu

There are 3 forms, **Entrance Information**, **Daily Information**, and **Late Events**.

1. **Entrance Information**

- a. The **Entrance Information** form should be completed for both 'enrolled' or 'eligible, not enrolled' patients.
- b. Your answers to questions 1 and 2 will distinguish between 'enrolled' or 'eligible, not enrolled' patients, and document the reason for non-enrollment:

1. Enrolled?	<input type="radio"/> Yes- skip to Q 3 <input type="radio"/> No- go to Q 2
2. Why was patient not enrolled?	<input type="radio"/> Parent refusal <input type="radio"/> Parent not informed of trial by surgeon choice <input type="radio"/> Surgeon uninformed about how to enroll patient <input type="radio"/> Managing physicians did not realize patient was eligible <input type="radio"/> Other _____

- c. You can then proceed to collect baseline data for both types of patients.
- d. When an 'eligible, not enrolled' patient is discharged or dies, please complete the following two questions, found on the last page of the form, and forward to us. This is the only way we will know whether these patients survive or not. This information will be captured on the **Daily Information** form for 'enrolled' patients (see #4, below).

INSTITUTION _____	MEDICAL RECORD NUMBER _____
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1. Date of discharge	___/___/___ (MM/DD/YYYY)
2. Date of death	___/___/___ (MM/DD/YYYY)

- e. Order of data collection for **Entrance Information** form:
 - i. Basic demographic information is collected first.
 - ii. Other information is grouped (roughly) into the following categories: medical history, medications, treatment, laboratory results. This should make it easier to abstract data from the chart or flow sheet.
 - iii. Blood culture results should only be entered as positive or negative- not pending. If the results are not available on the day you are completing the entrance form, please wait for the final results to be available and then send the completed form.
 - iv. Please send this form as soon as the data are collected. This will help us to maintain an accurate and timely enrollment count.
- f. Remember to keep copies of all forms for your records!

3. **Daily Information**

INSTITUTION _____		MEDICAL RECORD NUMBER _____			
POSTOPERATIVE DATE		___/___/___ (MM/DD/YYYY)		POSTOPERATIVE DAY	
ALIVE	<input type="radio"/> Yes <input type="radio"/> No	TRANSFERRED TODAY?	<input type="radio"/> Yes <input type="radio"/> No	DISCHARGED TODAY?	<input type="radio"/> Yes <input type="radio"/> No

- a. Please complete a **Daily Information** for each day this child is hospitalized, including the day the child dies, is transferred or is discharged from your institution.
 - i. Vital status transfer and discharge (if occurring) should be documented each day (see above.)
 - ii. Children who are transferred to other hospitals will most probably be discharged home from these institutions. Please notify us of the day of discharge or death if it occurs before discharge. This can be done by mail or phone.
- b. For convenience, please send us packages of **Daily Information** forms in bundles of no more than one month of data per child.

4. **Late Events Information**

- a. There is space to enter multiple late operations.
- b. Please complete and send this form as soon as the child dies, is transferred or discharged.
- c. Again, remember to keep copies of all forms for your records!

Thank you!