ChiLDREN **WEB-ENTRY** **ELASTIC** **Form 01E Eligibility**

A1. Site/Study ID #:___ ___ / **P**___ ___ ___ ___ A2. Visit Date:___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year) A3. Staff Initials:___ ___ ___

SECTION B: INCLUSION CRITERIA

B1. Is the Patient currently enrolled in longitudinal follow up in PUSH study at a site with transient elastography capability? 1. ☐ Yes 2. ☐ No → **Not eligible**

SECTION C: EXCLUSION CRITERIA

C1. Does the patient have presence of significant ascites that is detectable on physical examination? 1. ☐ Yes → **Not eligible** 2. ☐ No

C2. Does the Patient have active medical device implant, such as a pacemaker of defibrillator? 1. ☐ Yes → **Not eligible** 2. ☐ No

C3. Does the Patient have an open wound near sensor application site? 1. ☐ Yes → **Not eligible** 2. ☐ No

C4. Is the patient currently pregnant? 1. ☐ Yes → **Not eligible** 2. ☐ No

C5. Does the investigator believe participation in this study is not in the best interest? of the patient? 1. ☐ Yes → **Not eligible** 2. ☐ No

C6. Is the family unable or unwilling to sign the consent document or HIPAA release form? 1. ☐ Yes → **Not eligible** 2. ☐ No

C7. Is the patient unable or unwilling to tolerate the TE measurement procedure? 1. ☐ Yes → **Not eligible** 2. ☐ No

C8. Has the subject exited the PUSH study? 1. ☐ Yes → **Not eligible** 2. ☐ No

SECTION D: SUMMARY

D1. Subject is: 1. ☐ Eligible 2. ☐ Not eligible → **END**

Investigator's Signature Date (MM/DD/YYYY)

ChiLDREN WEB-ENTRY ELASTIC Form 29 TE

A1. Site/Study ID #:___ ___ / **P**___ ___ ___ ___ A2. Visit Date:___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year) A3. Staff Initials:___ ___ ___

SECTION B: Pregnancy and Ascites Evaluation

B1. Are you currently pregnant?
1. ☐ Yes → **DO NOT PERFORM TE** 2. ☐ No → Go to C1 3. ☐ Not Applicable (male subject or female is not of child bearing potential)

To be completed at the time of the annual physical exam research visit by CFLD investigator or attending physician.

B2. Ascites: 1. ☐ Present → **DO NOT PERFORM TE** 2. ☐ Absent

SECTION C: OPERATOR AND FASTING INFO

C1. Operator Name _____

C2. Has the subject been NPO (as defined by last solids or non water liquids) for 4 hours? 1. ☐ Yes 2. ☐ No

SECTION D: LIVER STIFFNESS MEASUREMENT

D1. Was the Fibroscan successfully completed? 1. ☐ Yes 2. ☐ No → Go to D1a

D1a. If not, provide reason (check all that apply)

- ☐ 1.Probe size related
- ☐ 2. Adherence behavior issues
- ☐ 3. Obesity
- ☐ 4. Ascites
- ☐ 5. Machine /Operator not available
- ☐ 6. Other: (Specify)_____

D2. Probe type (Check one): 1. ☐ S1 2. ☐S2 3. ☐ M. 4. ☐ XL

A1. Site/Study ID #:___ ___ / **P**___ ___ ___ ___ A2. Exit Date:___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year) A3. Staff Initials:___ ___ ___

To DCC ☐

SECTION B: FINAL PARTICIPANT STATUS

B1. Please identify the reason why the participant is leaving or discontinuing this study: **(check only one)**

1. ☐ Completed study → **END**
   - a. ☐ Finished follow up visits
   - c. ☐ Liver transplant
2. ☐ Transferred to another CFLD site → Specify site and date of transfer in B2
3. ☐ Ineligible prior to start of study (Was consented and then identified as ineligible) → Specify condition in B2
4. ☐ Violated eligibility condition after start of study → Specify condition in B2
5. ☐ Investigator withdrew subject from study for reason other than eligibility → Specify reason in B2
6. ☐ Participant voluntarily withdrew from study → Specify reason in B2
7. ☐ Lost to follow-up → **Complete only section C**
8. ☐ Death → **Complete only section D**
9. ☐ Other: _____ → Specify reason in B2

B2. Please specify the reason/cause/condition: _____

_____

B3. Participant has requested removal and destruction of his/her information from the database: 1. ☐ Yes 2. ☐ No

SECTION C: LOST TO FOLLOW-UP

C1. Reason for lost to follow-up: **(check only one)**

1. ☐ Care transferred to a Non-CFLD center
2. ☐ Lost contact
3. ☐ Other (Specify: _____)

C2. Date lost to follow up: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)

C3. Date of last contact: ___ ___ / ___ ___ / ___ ___ ___ ___ (Month / Day / Year)

A1. Site/Study ID #:___ ___ / **P**___ ___ ___ ___ A2. Visit Date:___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

SECTION D: DEATH

D1. Date of death: ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

D2. Cause of death: _____

D3. Complications present or treated at time of death: **(check all that apply)**

a. ☐ Pulmonary (Specify:_____)
b. ☐ Liver (Specify:_____)
c. ☐ Nutrition (Specify:_____)
d. ☐ Infectious (Specify:_____)
66. ☐ UNK

D4. Autopsy performed: 1. ☐ Yes 2. ☐ No → **END**

a. Patient's weight: ___ ___ ___.___kg **-OR-** ___ ___ ___.___lbs 99. ☐ Missing
b. Patient's height: ___ ___ ___.___cm **-OR-** ___ ___ ___.___in 99. ☐ Missing
c. Jaundice present: 1. ☐ Yes 2. ☐ No 3. ☐ Not reported on Medical Record
d. Liver findings: **(check all that apply)**
   a. ☐ None
   b. ☐ Cirrhosis
   c. ☐ Necrosis
   d. ☐ Other (Specify: _____)
   e. ☐ Not reported on Medical Record

Investigator Signature Date (MM/DD/YYYY)