

A1. Site/Study ID #: _____ / P _____ A2. Visit Date: _____ / _____ / _____
 Month Day Year A3. Staff Initials: _____
 A5. 7. Screening To DCC

SECTION B: INCLUSION CRITERIA

B1. Is the child 3 through 12 years of age? ELGB01 V2(3) 1. Yes 2. No → Not eligible

a. What is the child's date of birth? ELGB01AMM V2(2)/ ELGB01ADD V2(2)/ ELGB01AYY V2(4)/ ELGB01ADT
 Month Day Year

B2. Is the child enrolled in the CF/Toronto Registry? ELGB02 V2(3) 1. Yes 2. No → Not eligible

a. What is the child's CF/Toronto Center ID? __ ELGB02A V2(300)_____

B3. Was CF diagnosis confirmed by sweat chloride >60 mEq/L (on one occasion)?

1. Yes 2. No → Go to B4 66. UNK ELGB03 V2(3)

a. ELGB03A V2(10) _____ mEq/L

Date of testing: ELGB03AMM V2(2)/ ELGB03ADD V2(2)/ ELGB03AYY V2(4)/ ELGB03ADT
 Month Day Year

-AND/OR-

B4. Was CF diagnosis confirmed by at least two identified disease-causing mutations of the CFTR *with* evidence of end organ involvement?

1. Yes ELGB04 V2(3) 2. No Date of testing: ELGB04MM V2(2)/ ELGB04DD V2(2)/ ELGB034YY V2(4)/ ELGB03ADT
 Month Day Year

* Check all mutations that apply: (must check at least two)

	1	2
a.	ELGB04A1 V2(3)	ELGB04A2 V2(3) F508del
b.	ELGB04B1 V2(3)	ELGB04B2 V2(3) G542X
c.	ELGB04C1 V2(3)	ELGB04C2 V2(3) G551D
d.	ELGB04D1 V2(3)	ELGB04D2 V2(3) N1303K
e.	ELGB04E1 V2(3)	ELGB04E2 V2(3) W1282X
f.	ELGB04F1 V2(3)	ELGB04F2 V2(3) R553X
g.	ELGB04G1 V2(3)	ELGB04G2 V2(3) I507del
h.	ELGB04H1 V2(3)	ELGB04H2 V2(3) Y122X
i.	ELGB04I1 V2(3)	ELGB04I2 V2(3) W496X
j.	ELGB04J1 V2(3)	ELGB04J2 V2(3) E822X
k.	ELGB04K1 V2(3)	ELGB04K2 V2(3) 2184delA
l.	ELGB04L1 V2(3)	ELGB04L2 V2(3) R1162X
m.	ELGB04M1 V2(3)	ELGB04M2 V2(3) G85E
n.	ELGB04N1 V2(3)	ELGB04N2 V2(3) 394delTT
o.	ELGB04O1 V2(3)	ELGB04O2 V2(3) R560T
p.	ELGB04P1 V2(3)	ELGB04P2 V2(3) R1066C
q.	ELGB04Q1 V2(3)	ELGB04Q2 V2(3) 2143delT

	1	2
y.	ELGB04Y1 V2(3)	ELGB04Y2 V2(3) 3905insT
z.	ELGB04Z1 V2(3)	ELGB04Z2 V2(3) 711+1G>T
aa.	ELGB04AA1 V2(3)	ELGB04AA2 V2(3) 1609delCA
bb.	ELGB04BB1 V2(3)	ELGB04BB2 V2(3) 1717-1G>A
cc.	ELGB04CC1 V2(3)	ELGB04CC2 V2(3) 1898+5G>T
dd.	ELGB04DD1 V2(3)	ELGB04DD2 V2(3) 296+1G>C
ee.	ELGB04EE1 V2(3)	ELGB04EE2 V2(3) 1898+1G>T
ff.	ELGB04FF1 V2(3)	ELGB04FF2 V2(3) 2183AA>G
gg.	ELGB04GG1 V2(3)	ELGB04GG2 V2(3) 1898+1G>A
hh.	ELGB04HH1 V2(3)	ELGB04HH2 V2(3) 2789+5G>A
ii.	ELGB04II1 V2(3)	ELGB04II2 V2(3) 621+1G>T
jj.	ELGB04JJ1 V2(3)	ELGB04JJ2 V2(3) 2869insG
kk.	ELGB04KK1 V2(3)	ELGB04KK2 V2(3) 2751+2T>A
ll.	ELGB04LL1 V2(3)	ELGB04JLL2 V2(3) 1811+1.6kbA>G
mm.	ELGB04MM1 V2(3)	ELGB04JMM2 V2(3) R1070Q-S466X
nn.	ELGB04NN1 V2(3)	ELGB04JNN2 V2(3) 1811+1,6kbA>G
oo.	ELGB04OO1 V2(3)	ELGB04JOO2 V2(3) 3120+1G>A

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A5. 7. Screening

r. ELGB04R1 V2(3) ELGB04R2 V2(3) K710X	uu. ELGB04UU1 V2(3) ELGB04UU2 V2(3) Other (Specify: ELGB04QQSP V2(500)
s. ELGB04S1 V2(3) ELGB04S2 V2(3) R1158X	vv. ELGB04VV1 V2(3) ELGB04VV2 V2(3) Other (Specify: ELGB04VVSP V2(500)
t. ELGB04T1 V2(3) ELGB04T2 V2(3) 1078delT	pp. ELGB04PP1 V2(3) ELGB04PP2 V2(3) R334W
u. ELGB04U1 V2(3) ELGB04U2 V2(3) 3659delC	qq. ELGB04QQ1 V2(3) ELGB04QQ2 V2(3) R347P
v. ELGB04V1 V2(3) ELGB04V2 V2(3) 2184insA	rr. ELGB04RR1 V2(3) ELGB04RR2 V2(3) A455E
w. ELGB04W1 V2(3) ELGB04W2 V2(3) Q890X	ss. ELGB04SS1 V2(3) ELGB04SS2 V2(3) R117H
x. ELGB04X1 V2(3) ELGB04X2 V2(3) S549N	tt. ELGB04TT1 V2(3) ELGB04TT2 V2(3) 3849+10kbC>T

*These mutations are not associated with pancreatic insufficiency.

B5. Has the child been diagnosed with pancreatic insufficiency, defined by fecal elastase <100 mg/gm (at any time)?

1. Yes 2. No → Go to B6 66. UNK ELGB05 V2(3)

a. ELGB05A V2(10) mg/gm

Date of testing: Date of testing: ELGB05AMM V2(2)/ ELGB05ADD V2(2)/ ELGB05AYY V2(4)/ ELGB05ADT
 Month Day Year

-AND/OR-

B6. Has the child been diagnosed with pancreatic insufficiency defined by 72 hour fecal fat (at any time) with coefficient of fat absorption <85%?

1. Yes 2. No → Go to B7 66. UNK

a. ELGB06A V2(10) %

Date of testing: ELGB06AMM V2(2)/ ELGB06ADD V2(2)/ ELGB06AYY V2(4)/ ELGB06ADT
 Month Day Year

-AND/OR-

B7. Has the child been diagnosed with pancreatic insufficiency defined by a CFTR Mutation associated with pancreatic insufficiency?*

1. Yes ELGB07 V2(3) 2. No a. ELGB07A V2(10)%

Date of testing: ELGB07AMM V2(2)/ ELGB07ADD V2(2)/ ELGB07AYY V2(24)/ ELGB07ADT
 Month Day Year

*Responses identified in B4 with the asterisks (pp,qq,rr,ss,tt) do not qualify in the diagnosis of pancreatic insufficiency.

B8. Have the child's parent(s)/guardian(s) provided informed written consent? ELGB08 V2(3) 1. Yes 2. No → Not eligible

SECTION C: EXCLUSION CRITERIA

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

A5. 7. Screening

- C1. Does the child have known cirrhosis? ELGC01 V2(3) 1. Yes → Not eligible 2. No
- C2. Does the child have short bowel syndrome defined as not on full enteral feeds by 3 months of age? ELGC02 V2(3) 1. Yes → Not eligible 2. No
- C3. Does the child have another serious disease (including other known causes of chronic liver disease) that precludes participation in this study? ELGC03 V2(3) 1. Yes → Not eligible 2. No
- C4. Does the investigator believe participation in this study is not in the best interest of the patient? ELGC04 V2(3) 1. Yes → Not eligible 2. No
- C5. Is the family unable to comply with the follow-up described in the protocol? ELGC05 V2(3) 1. Yes → Not eligible 2. No
- C6. Is the family unable to sign the consent document or HIPAA release form? ELGC05 V2(3) 1. Yes → Not eligible 2. No
- C7. Has the child ever had a culture positive for B. cepacia? ELGC07 V2(3) 1. Yes → Not eligible 2. No

SECTION D: SUMMARY

D1. Subject is: 1. Eligible 2. Eligible by exemption 3. Not eligible → END ELGD01 V2(3)

ELGINSIG V2(3)

ELGSIGMM V2(2)/ ELGSIGDD V2(2)/ ELGSIGYY V2(4)/ ELGSIGDT

Investigator's Signature

Date (MM/DD/YYYY)

Comment ELGCMNT V2(800)