

A1. Site/Study ID #: _____ / _____

A2. Date: _____ / _____ / _____
Month Day Year

A3. Study Staff ID/Initials: _____

A4. Visit: BL 2W 1 2 3 6 OR Age: _____ mo/yrTo DCC **SECTION B: FINAL SUBJECT STATUS**B1. Will the subject remain in the database study (P003)? 1. No → **Complete Form 35 Final Status** 2. Yes
FNLB01 V2(2)B2. Please identify the reason why the subject is leaving the P004 Study (*check only one response below*): FNLB02 V2(2)

1. Completed the P004 Study (reached age 2)
2. Transferred to another BARC site → Specify site and date of transfer in B3 → **END**
3. Investigator withdrew subject from study for reason other than eligibility → Specify reason in B3 and complete B4 – B5 → **END**
4. Subject voluntarily withdrew from study → Specify reason in B3 and complete B4 – B5 → **END**
5. Subject refused further treatment → Specify reason in B3 and complete B4 – B5 → **END**
6. Lost to follow-up → **Complete Form 35 Final Status**
7. Death → **Complete Form 35 Final Status**
8. Other: _____ FNLB028OT V2(200) → Specify reason in B3 and complete B4 – B5 → **END**

B3. Please specify the reason/cause/condition: FNLB03 V2(500)

B4. Subject has requested removal of his/her information from the database: 1. No 2. Yes
FNLB04 V2(2)B5. Subject has requested removal of his/her samples from the repository. 1. No 2. Yes
FNLB05 V2(2)Investigator/Coordinator Signature: _____ FNLINSIG V2(2) Date: _____ FNLSIGMM V2(2)/ FNLSIGDD V2(2)/ FNLSIGYY V2(4)/ FNLSIGDT
Month Day Year
FNLMMNT V2(800)