

## **INFORMED CONSENT & FECAL DONOR AGREEMENT FORM**

In accordance with the Code of Federal Regulations (45 CFR 46.116), TechLab is required to make the following information available to fecal donors:

(a) Basic elements of informed consent

- (1) Your feces will be used in researching the composition and activity of normal fecal bacteria. Your contribution to the project requires you to provide about three times each yearly for three years. The study will last 3 years.
- (2) There are no foreseeable risks or discomforts associated with donating feces.
- (3) A monetary payment (\$20<sup>00</sup>/fecal donation) will be made by check to adult donors and to the parents or legal guardians of those <18 years old. No benefits to individual donors will result from the study.
- (4) There are no suitable alternatives to feces in this study; no treatment is involved.
- (5) Donors will be given a code number so that their sample of feces cannot be identified as having come from any named individual. Similarly, it will not be possible to link any results with a particular named individual. TechLab scientists will not be able to identify any donor by names.
- (6) The study involves minimal risk to donors.
- (7) In the event that donors have questions, or that they sustain any injury related to the donation of their feces, they should contact:

Dr. Robert J. Carman,  
TechLab, Inc.  
2001 Kraft Drive,  
Blacksburg, VA 24060-6358

Phone: (800) TECHLAB or  
(540) 953-1664  
Fax: (540) 953-1665  
Email: [rjcarman@techlab.com](mailto:rjcarman@techlab.com)

- (8) Participation in the study is entirely voluntary; refusal to participate will involve no penalty or loss of benefits to which the donors are otherwise entitled. Donors can withdraw from the project at any time without loss of benefits to which they would otherwise be entitled.

(b) Additional elements of informed consent

- (1) There is no foreseeable risk to donors, pregnant or not, and below 18 years or not, associated with defecation.
- (2) In the event that a donor is to consume antibiotics during the 12-week period preceding any donation, or they experience any intestinal condition believed by TechLab to alter or potentially to alter intestinal microflora, that donor may be excluded, either temporarily or permanently, from the study. A list of conditions, that may be incomplete, and that may lead to this course is included in the Fecal Donor Questionnaire Form.

- (3) There are no foreseeable additional costs associated with participation in this study.
- (4) Any significant findings made during the study that may relate to the donors' continued participation in the study will be provided to all donors.
- (5) During each year for three years TechLab estimates that up to 10 donors may be required.

Summary

TechLab, Inc. uses feces from healthy persons for research purposes. The research may be grant-funded or "for profit" research paid for by a TechLab client. Insofar as the samples are from "healthy" donors, the area of research is that of normal intestinal biology, though the samples may be used to establish baselines for comparison with data derived from diarrheic samples. No diagnoses will be made. Individual donors' samples will not be linked to names or other identifiers, beyond the data collected in the Fecal Donor Questionnaire. A code number identifies donors. Samples can be linked to a donor's code number, not the donor's identity.

I understand that providing fecal samples to TechLab, Inc. involves no risk to my health and that all the information provided above and obtained through the use of my sample(s) will remain anonymous. I have been informed of how my specimen will be used.

I have or will receive payment by check, not to exceed a total of \$20<sup>00</sup> from TechLab for each sample. I have completed a Donor Questionnaire Form and have read and understood this form.

I can call Bob CARMAN at 1-800 TECHLAB if I need to discuss anything about this matter with a representative of TechLab.

Signature of Donor	Printed name of donor	Date
Address of donor		

Signature of Parent or Legal Guardian (please indicate which) if Donor <18 years old	Printed name of Parent or Legal Guardian if Donor <18 years old	Date
Address of Legal Guardian if Donor <18 years old		