

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 and serum will be used in researching *C. difficile* diarrhea. Our purpose is to assay your antibodies towards various *C. difficile* antigens. Scientists believe the higher your antibodies levels are, the less likely it is you will be susceptible to both initial and relapsing attacks of *C. difficile* diarrhea. It is this idea that we want to pursue using your samples. Your contribution to the project requires you to provide one or more serum and fecal samples to TechLab. The study will last 12 months.
- (2) There are no foreseeable risks or discomforts associated with donating feces. The risks associated with providing a serum sample are.....
- (3) A monetary payment (\$20⁰⁰) will be made 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 serum and feces in this study; no treatment is involved.
- (5) Donors will be given a code number so that their feces and serum 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

(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 the 12 month study period TechLab estimates that up to 25 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 will 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 their name.

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, not to exceed a total of \$20⁰⁰ 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

Prepared by Carman 09/17/03; revised 12/09/05