

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 intestinal inflammation and antibiotic associated diarrheas. Our purpose is to: 1) establish standard measurements of markers of inflammation; 2) establish standard signals while developing immunoassays and 3) test non-specific reactivity in immunoassays. Your contribution to the project requires you to provide one or more samples of fresh feces to TechLab. The study will last 12 months.
- (2) There are no foreseeable risks or discomforts associated with donating feces.
- (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 feces in this study; no treatment is involved.
- (5) Donors will be given a code number to minimize the possibility that their sample of feces can be identified as having come from any named individual.
- (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:

James Boone
TechLab, Inc.
2001 Kraft Dr.
Blacksburg, VA 24060

Phone: (800) TECHLAB or
(540) 953-1664
Fax: (540) 953-1665
Email: jhboone@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 has consumed 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 inflammation, 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 50 donors may be required.

Summary

TechLab, Inc. uses feces from voluntary donors for research purposes. The research may be grant-funded or "for profit" research paid for by a TechLab client.

Samples will be used to establish standard levels of inflammatory markers in representative healthy donors and those with specific disease states. Samples may be used for comparison with data derived from diarrheic samples. No diagnoses will be made. Individual donors' samples will be linked to a code number to minimize the possibility a researcher working with a sample will be able to link the sample to the donor.

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 James Boone at 1-800 TECHLAB if I need to discuss anything about this matter with a representative of TechLab.

Signature of Donor

Date

Printed Name

Signature of Parent or Legal Guardian if
Donor <18 years old

Date

Printed Name

Parent / Legal Guardian
(please indicate which)

Prepared by Whitlock 02/16/09