Baylor College of Medicine

ALKEK CENTER FOR METAGENOMICS AND MICROBIOME RESEARCH

Sample Collection and Transport

Before collecting human samples for metagenomics and microbiome analysis, the investigator will be responsible of obtaining IRB approval for the study and providing informed consent form to the subjects.

REGULATORY REQUIREMENTS

1. PROTECTION OF HUMAN SUBJECTS:

The study protocol, informed consent documents and all types of subject recruitment or advertisement information must be submitted to the IRB for review and must be approved prior to study initiation. Any amendments to the protocol and/or consent form must also be approved by the IRB prior to implementing any changes in the study.

The investigator is responsible for keeping the IRB apprised of the progress of the study and of any changes made to the protocol as deemed appropriate, but in any case, at least once a year. The investigator must also keep the IRB informed of any serious adverse events, unanticipated problems, or protocol deviations resulting in serious or severe adverse events.

To protect the privacy of study subjects, the Study ID code list should be maintained in a secure location that is separate from the regulatory binder. Copies of any identifying documents, e.g., documents containing the subject's name, should also be maintained in a secure location that is separate from both the regulatory binder and the subjects' individual study binders.

2. INFORMED CONSENT:

Informed consent is an ongoing process that begins with the first contact with a prospective subject and continues until the study is completed. The consent form provides information about the study, including the rights of the subject and the risks and benefits involved in participating in the study. The consent form also documents the subject's agreement to participate. All procedures, subject obligations, and subject rights should be explained to the subject in easily understood language. During the explanation of the study and during the actual study, the subject is entitled to privacy and respect. The investigator or a designee may present the information and administer the consent. The investigator/designee should be well versed in the protocol and able to answer questions about the study procedures. The investigator/designee presenting the study should encourage the prospective subject to ask questions during this introduction to the study and anytime during his/her participation. Following the information presentation, the administrator should feel confident that the subject understands the study before the consent form is signed and before final inclusion into the study.

Please have in mind the following when shipping samples to CMMR:

- Samples should be free of Identifiers.
- No clinical information should come with samples
- Samples should be identified by a numeric code

1. **Sample size:** Determined by the type of sample.
2. **Storage before transport**: From the time of collection, samples can be stored for short-term at-20°C for 7 days and at -80°C for a longer term.
3. **Packing**

a) Please include with the samples an excel form indicating the following:
   - Sample ID and please list all the
   - Any parameters needed for analysis such as:
     - Demographic information
     - Disease or treatment group
     - Other variables

b) **Outer packing**: Samples should be secured in a box or zip-lock bag and placed in a Styrofoam box with plenty of dry ice. The Styrofoam box should be contained in a cardboard box for protection. Please follow the guidelines for transportation of Biological samples from your currier.

c) Samples should be shipped preferably early in the week to avoid weekend deliveries.

d) Please notify us via email of the day of shipment, courier, contact information and tracking numbers along with a spreadsheet containing a sample log.

FEDEX GUIDELINES

www.fedex.com/us/packaging/guides/Clinical_fxcom.pdf

http://images.fedex.com/downloads/shared/packagingtips/pointers.pdf

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