Background on Template for Informed Consent Form for HMP Demonstration Projects (RFA #RFA-RM-08-012)

The Informed Consent Process

Informed consent involves two essential components: a document (consent form) and a process. The consent *form* provides a description of the research project (including the purpose of the research, the study procedures, potential benefits and risks, alternatives to participation, the voluntary nature of participation, etc.) and explains the individual's rights as a research participant. It is just one part of the informed consent *process*, which generally involves a series of conversations between the research team and participants. The informed consent process provides potential participants with more extensive information about the project to help them make educated decisions about whether to participate. It frequently also involves ongoing interaction with participants once they have enrolled. Informed consent is thus an ongoing, interactive process—not a one-time information session followed by the signing of a document.

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Purpose of the Template

A framework for an informed consent form has been developed for use as a template by investigators submitting applications for Human Microbiome Demonstration Projects under RFA-RM-08-012. The document was designed with input from the HMP Working Group on Informed Consent. It is based on approaches used in other NIH large-scale community resource genomics projects that involve the deposition of extensive genomic data in databases and broad data sharing over the Internet with multiple investigators for use in multiple studies.

This generic form is offered only as framework to assist or inform investigators. It is not intended to be prescriptive. It should rather be considered primarily as a *starting point*, to provide a guide to the basic elements that should be considered when developing a consent form for a HMP Demonstration Project. Each investigator will necessarily need to customize the document to fit the aims of the particular project. In addition, many institutions have special requirements (for example, regarding the inclusion of particular

"boilerplate" language on certain topics); these institutional requirements may also necessitate some changes to the structure or content of the template.
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Essential Elements in Consent Forms for HMP Demonstration Projects

The template is consistent with, and intended to be complementary to, applicable U.S. regulations, including 45 CFR 46, 21 CFR 50 and 21 CFR 56, and other guidance from the Office for Human Research Protections and the Food and Drug Administration. Foreign investigators submitting applications for HMP Demonstration Projects may need to modify the template substantially, in accordance with their own national and local cultural norms and applicable legislation, regulations, or policy.

45 CFR 46.116(a) lists eight essential elements of informed consent. In addition to including those elements in the consent form (and, for foreign investigators, satisfying any other applicable legal guidelines), consent forms for HMP Demonstration Projects should generally include discussion of each the following topics:

- the plans to deposit data in scientific databases available over the Internet (with special precautions in place to protect privacy);
- the opportunity that will be provided to many investigators in many institutions around the world to study the data for a long time to come;
- the inevitability that human DNA will be collected, either intentionally or as a contaminant, with microbial samples, any special privacy risks associated with that, and the measures that will be taken to minimize those risks;
- any plans to make cell lines, and the consequence that an unlimited amount of the participant's DNA will potentially become available;
- the issues that may be raised by sharing the samples with other investigators (e.g., who will have access to the samples, for what purposes, and with what controls);
- the circumstances, if any, under which investigators may re-contact the participant to ask for more samples or information;
- the plans for the handling of any mandatory reporting requirements (e.g., for sexually transmitted diseases or other communicable diseases discovered in the course of the study);
- the possibility that companies may study the data (or the samples) and that if any commercially valuable products result from these studies, participants will not receive any of the profits;

- the inability of participants to withdraw their information from the databases once their samples have been studied.

Depending on the nature of the specific Demonstration Project being proposed, discussion of additional topics in the consent form may also be necessary.

In addition, except in the rare case where the Demonstration Project as proposed would pose no risk that the investigator might at some point be asked to disclose a participant's identity in a legal proceeding, investigators should consider applying for a Certificate of Confidentiality from the appropriate NIH institute as an additional way to protect the research participants' identities. A description of the protections provided by the Certificate of Confidentiality should also be included in the consent form.

Please contact us if you have any questions relating to informed consent for a proposed Demonstrate Project. We are happy to work with investigators, IRBs, and recruiters to help them in the development or implementation of consent processes and consent forms. Investigators will be asked to submit their consent forms to NIH for review before submitting them to their IRBs or ethics committees for final approval.
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Other Considerations

The template is designed to be used in connection with the collection of samples from *healthy volunteers* (controls). Investigators will need to modify the template for participants who are being recruited as individuals with a particular condition or disease (cases).

The template is designed to be used in connection with the collection of *new samples*. Investigators proposing to obtain re-consent from participants who are already enrolled in existing studies will need to modify the template accordingly.

The template is designed to be used in connection with the collection of samples from *legally competent adult participants.* Investigators proposing to collect samples from children or from other individuals who lack legal competency will need to modify the template accordingly. The consent process and consent form used to collect samples from children or others who lack legal competency should specifically describe the unique risks associated with sampling from such individuals, and what specific measures will be taken to protect against those risks.

The template is designed with the assumption that *blood samples for human host DNA analysis* will be collected in addition to microbial samples. Investigators proposing projects that will not involve the collection of human DNA do not need to include the language in the document that describes the unique privacy and other risks associated with human DNA sampling and the measures that will be taken to minimize those risks.

Some investigators proposing projects that will involve the collection of human DNA may choose to use *two separate consent forms*—one for the microbial sampling and one

for the blood sampling. The risks associated with the two types of sampling are quite different, and splitting consent to the two types of sampling into two separate documents could shorten the length of each document considerably, thus making each document easier to follow and understand.

Finally, this template is written at a reading level (above high school) that may be too high for some populations. *Investigators are encouraged to explore ways to shorten or simplify the language in the consent form, so long as this can be done without omitting essential elements or other important information.*
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