DAIDS SAMPLE Informed Consent Template
Stored samples and Associated Health Information for future Research Use
(Version 1.0 Final, Date: November 5, 2012)
—INSTRUCTIONS—

This template addresses the storage of unused (leftover) samples and the collection and storage of extra samples, along with the participants' associated health information, for future research. This research may include genetic testing such as genome-wide association studies (GWAS) and DNA sequencing efforts (whole genome, exome, deep sequencing, etc.).

This template does NOT address samples stored for batched testing that is required as part of the main research study and is to be completed during the study data analysis. This situation is addressed in the DAIDS SAMPLE INFORMED CONSENT TEMPLATE FOR GENERAL USE (under development).

NOTES FOR SAMPLE INFORMED CONSENT AUTHORS:

- Throughout this template, instructions and examples are provided using *(italics)*. Once the informed consent is complete, remove all the instructions highlighted in yellow.
- Throughout this template, there are some instructions labeled as ***For Local Investigators and CRS personnel.*** These instructions should be kept in the protocol specific sample informed consent form and should be addressed directly by sites in their site specific informed consent forms.
- Make sure that information placed in the protocol specific sample informed consent form matches the protocol content.
- The first person "I" and second person "YOU" are used throughout the template to identify the research study participant; however, for research with children, these terms should be modified as appropriate, e.g., Your Child, Your Baby, You and Your Child, You and Your Baby, etc.
- The term "Researchers" used throughout this document refers to (1) The investigators collecting, storing, and/or using the samples and information for future research; and (2) Any scientists/investigators or clinical staff who will be conducting the future research.

GENERAL INSTRUCTIONS TO CLINICAL RESEARCH SITES:

- Customize template language in any section of this template to fit the main research study. Whenever possible, culturally appropriate language and/or context specific language should be used. This context specific language includes the use of local words and sentence structure.
- The informed consent form is a tool for the larger informed consent process for each protocol. Therefore, the informed consent form can be supplemented with IRB/EC approved culturally appropriate non-written methods of communication (e.g., videos, flipcharts, etc.) as well as additional documents/materials (e.g., participant information sheet, medical glossaries, etc.)
- For studies that involve children, the IRBs/ECs should consider the appropriateness of the continued maintenance and sharing of the samples and data when the child reaches the legal age of consent.

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