



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.

TEMPLATE's Table of Contents

- | | |
|---|---|
| 1. Request a short version of the research study title in layman's terms. | 12. Can I change my mind about the storage and use of my samples and information? |
| 2. What samples will researchers collect and store? | 13. What are the costs to me? |
| 3. Where will researchers store my information and samples? | 14. Will I receive any payment? |
| 4. How will researchers use my information and samples? | 15. Who should I contact if I think I am injured during the collection of extra samples? |
| 5. What genetic testing will researchers do with my samples? | 16. What are my rights and who should I contact if I have questions about future research using my samples and information? |
| 6. What other research could researchers do with my information? | 17. Can I choose the types of future research? |
| 7. How long will researchers store my samples for future research? | 18. Will researchers be able to use my stored samples and information for other types of future research? |
| 8. What are the risks of storing my samples and information for future research? | 19. Do I want researchers to contact me if they find something important about my health? |
| 9. What are the benefits of storing my samples and information for future research? | 20. How do I confirm my permission to collect, store and use my samples and information in future research? |
| 10. How will researchers keep my information confidential? | |
| 11. What other choices do I have? | |