DAIDS PROTOCOL SPECIFIC INFORMED CONSENT TEMPLATE—General Use
(FINAL Version 1.0 Date: JULY 24, 2013)
—INSTRUCTIONS PAGE—

NOTES For Informed Consent Authors:

- The protocol specific sample informed consent form created using this template should match the protocol content.
- Throughout this template, instructions and examples are provided in *(italics)*. There is text using *(italics)* to mark subsections. There is also text in *(italics)* for the risk summary table guidelines located at the end of the entire risk section of this template. Once you have completed the protocol specific informed consent form, remove all the instructions highlighted in yellow, blue, or purple. 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 clinical research sites (CRS) in their site specific informed consent forms.
- 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 protocol chairs, CRS Principal Investigators, scientists, investigators, or clinical staff, who will be conducting the study. The term "study staff" used throughout this template refers to anyone at the CRS who is involved with the study at the site level and is listed in the CRS' delegation log.
- This template does not address the storage of unused (leftover) samples or the collection and storage of extra samples for future research. These situations are addressed in the separate *DAIDS SAMPLE INFORMED CONSENT TEMPLATE STORED SAMPLES AND ASSOCIATED HEALTH INFORMATION FOR FUTURE RESEARCH USE*.

NOTES For Local Investigators and CRS personnel:

- Whenever possible, culturally appropriate language or context specific language should be used. This context specific language should include the use of local words and sentence structure. Customize language in this template to suit each study.
- Some social harms or social risks, such as loss or breach of privacy may result in embarrassment, stigmatization, loss of current or future employment, deterioration of the standing in the community, ineligibility for insurance, criminal prosecution, etc. Information regarding alcohol or drug abuse, mental illness, HIV status, illegal activities, and sexual behavior are areas of particular sensitivity. Therefore, special attention should be given to augment and specifically define the social risks described in the informed consent form at the local level of implementation of the protocol.
- 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 and materials e.g., participant information sheet, medical glossaries, etc. A good informed consent process includes some type of "Assessment of Understanding" (AoU) given to participants. Various AoU-methodologies can be used to evaluate understanding, e.g., open ended, true or false, and multiple choice questions; or a combination.
- For studies that involve children, the local IRB/EC is responsible for determining: (1) when children are capable of providing assent and how and whether assent must be documented; (2) when the permission of one parent or legal guardian is sufficient; and (3) when the permission of both parents or legal guardians is needed. These IRB's/EC's determinations impact the informed consent process and the required signatures on the informed consent form (45 CFR 46.408). Also see DAIDS policies for protocol and site for research on children (DAIDS Clinical Site Implementation and Operations)
- The regulations of the U.S. Department of Health and Human Services (HHS) convey that the consent process should be done in a language understandable to the prospective participant and, in most situations, documented in writing. The prospective participant should be presented with a complete consent form, such as the form generated using this template. Alternatively, a short consent form written in a language spoken by the prospective participant could be used. This short form should state that the elements of consent have been presented orally using a written summary. This summary could be the IRB/EC-approved site specific informed consent form for the study (sample short form consent). When the short form is used, a witness who is fluent in both the language of the summary, and the language of the short consent form, is required. The prospective participant must be given copies of the short form and the summary. The form should be signed or marked by the prospective participant, or his/her legally authorized representative, and the witness. The summary should be signed by the study staff obtaining consent and the witness. If the study staff obtaining consent is assisted by a translator, the translator may serve as the witness (45 CFR 46.117).
- According to the U.S. Food and Drug Administration (FDA) Guidance, an illiterate prospective participant can be enrolled in a study by "making a mark" on the site specific consent form, as long as this practice is consistent with applicable local law. Similarly, a prospective participant who is physically unable to talk or write, so he/she cannot make a mark, but who understands the spoken language used during the verbal consent process and also understands the study's concepts, risks and benefits, can be enrolled. In this instance, the prospective participant would somehow have to be able to indicate approval or disapproval to enroll in the study, as long as this procedure is consistent with local law. In both these cases, there should be a witness present during the entire consent process who signs the site specific informed consent form (FDA guide to informed consent).