# Final Protocol Template Language for Protocol Registration (April 2010)

The following language should be included under the Protocol Registration Section or equivalent section in each protocol.

**Note: Each protocol should include 3 paragraphs (intro, initial reg and amendment reg).**

**If there are any restrictions related to protocol registration (i.e. site implementation plan required before protocol registration is allowed to occur OR the study is only open to U.S. sites) this information should be included in the Protocol Registration section of the protocol or at the beginning of the protocol document.**

## Intro Paragraph – to be Included in Every Protocol:

Prior to implementation of this protocol, and any subsequent full version amendments, each site must have the protocol and the protocol informed consent form(s) approved, as appropriate, by their local institutional review board (IRB)/ethics committee (EC) and any other applicable regulatory entity (RE). Upon receiving final approval, sites will submit all required protocol registration documents to the DAIDS Protocol Registration Office (DAIDS PRO) at the Regulatory Support Center (RSC). The DAIDS PRO will review the submitted protocol registration packet to ensure that all of the required documents have been received.

**Note: Insert appropriate language once protocol registration requirements have been determined at scientific review or regulatory review.**

## Initial Registration Language – to be Included in Every Protocol:

For protocols that WILL have site-specific informed consent forms (ICFs) reviewed by the DAIDS PRO:

Site-specific informed consent forms (ICFs) WILL be reviewed and approved by the DAIDS PRO and sites will receive an Initial Registration Notification from the DAIDS PRO that indicates successful completion of the protocol registration process. A copy of the Initial Registration Notification should be retained in the site's regulatory files.

Or

For protocols that WILL NOT have site specific ICFs reviewed by the DAIDS PRO:

Site-specific informed consent forms (ICFs) WILL NOT be reviewed or approved by the DAIDS PRO, and sites will receive an Initial Registration Notification when the DAIDS PRO receives a complete registration packet. Receipt of an Initial Registration Notification indicates successful completion of the protocol registration process. Sites will not receive any additional notifications from the DAIDS PRO for the initial protocol registration. A copy of the Initial Registration Notification should be retained in the site's regulatory files.

## Amendment Registration Language – to be Included in Every Protocol Unless Site Specific IFCs will be Reviewed:

Upon receiving final IRB/EC and any other applicable RE approval(s) for an amendment, sites should implement the amendment immediately. Sites are required to submit an amendment registration packet to the DAIDS PRO at the RSC. The DAIDS PRO will review the submitted protocol registration packet to ensure that all the required documents have been received. Site-specific ICF(s) WILL NOT be reviewed and approved by the DAIDS PRO and sites will receive an Amendment Registration Notification when the DAIDS PRO receives a complete registration packet. A copy of the Amendment Registration Notification should be retained in the site's regulatory files.

For additional information on the protocol registration process and specific documents required for initial and amendment registrations, refer to the current version of the DAIDS Protocol Registration Manual.

## Amendment Registration Language – Only to be Included in a Protocol if it is Determined at the Time of Regulatory Review that Site Specific ICF Review is Required:

Upon receiving final IRB/EC and any other applicable RE approval(s) for this amendment (Version XXX), sites should implement the amendment immediately. Sites are required to submit an amendment registration packet to the DAIDS PRO at the RSC. Site-specific ICF(s) WILL be reviewed and approved by the DAIDS PRO and sites will receive an Amendment Registration Notification from the DAIDS PRO that approves the site specific ICFs and indicates successful completion of the amendment protocol registration process. A copy of the final amendment Registration Notification issued by the DAIDS PRO should be retained in the site's regulatory files.

For additional information on the protocol registration process and specific documents required for initial and amendment registrations, refer to the current version of the DAIDS Protocol Registration Manual.