Prometheus
Laboratories

**Please fill in, sign, and fax to 858-882-5961** **Date:____/_____/_____**

## Informed Consent Compliance – Hospital/Laboratory/Physician for Genetic Testing*

Name of Hospital / Laboratory/Practice_____("Client")

Hospital / Laboratory/Practice Phone Number _____

Address _____

City, State & Zip _____

* When Prometheus Laboratories Inc. receives genetic test orders for PROMETHEUS IBD sgi® Diagnostics, Celiac Genetics, Celiac PLUS, TPMT Genetics, Lacto*TYPE*® or PROMETHEUS Crohn's Prognostic from our hospital, laboratory and/or physician clients, we require assurance that they have a process in place to comply with applicable informed consent requirements related to such testing.

For all genetic testing submitted to Prometheus by Client, I represent that Client has an appropriate process in place to comply with informed consent requirements under applicable state laws and/or regulations that require medical professionals who order genetic testing to obtain the informed consent of the patient for such testing.

**This attestation remains in effect until an updated form is submitted.**

Signature of hospital / laboratory official / physician: _____

Print Name: _____

Title of hospital / laboratory official/: _____

### Background

Some state laws require that individuals (or their authorized representative) provide written informed consent (some states permit oral informed consent) to the physician ordering genetic testing and/or releasing test results.

Where applicable, the individual (or authorized person) must sign and date a consent form, or otherwise provide informed consent that includes a statement:

- of test purpose if the test is to determine whether the patient may have a variant in the gene(s) being treated, which has been found to be associated with this condition;
- that the ordered test will only test for the specific condition and will not detect ALL possible variants within this gene, nor will it detect variants in other genes;
- that prior to obtaining the written consent, a qualified healthcare professional discussed with the patient the genetic test ordered and described the steps involved in the test, the constraints of the procedure, and it's accuracy;
- that the patient was advised by a qualified medical professional of the risks and benefits of genetic testing and advised of the significance of a positive and negative test result;
- that the patient understands that a positive test result is an indication that the patient may be predisposed to, or have, the condition being tested for;
- that the patient understands that the test may fail, that the results may be non-informative or not predictive for his/her case, and that these tests may reveal information that is unrelated to their intended purpose;
- authorizing Prometheus to report his/her test results directly to the ordering healthcare professional;
- acknowledging that the genetic specimens will be destroyed within 60 days of test completion;
- acknowledging that the written consent does not authorize the use or release of any other medical information unrelated to the genetic test being ordered; and
- that the patient understood that he/she could seek professional genetic counseling prior to signing the informed consent and undergoing the testing procedure and received written information identifying a genetic counselor or medical geneticist by his/her treatment provider.