PROMETHEUS®
Therapeutics & Diagnostics
For the person in every patient®

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.