SCHULMAN APPROVED
IRB #201407047
DATE: April 12, 2017

Patient Information and Authorization for Use/Disclosure of Data Addendum FOR PATIENTS ON IMM THERAPY AT ENROLLMENT

A Long-Term Non-Interventional Registry to Assess Safety and Effectiveness of HUMIRA® (Adalimumab) in Patients with Moderately to Severely Active Ulcerative Colitis (LEGACY)

Investigator:	Satinder Gill, MD
Investigator Address:	Emeritas Research Group 19455 Deerfield Ave., Suite 201 Leesburg, Virginia 20176
Telephone Number**:**	(703) 268-3542 - 24- hour number (703) 723-3670 - office number

Dear Study Subject,

You are currently a participant in the above non-interventional (observational) registry study which aims to collect information on approved medications for ulcerative colitis (UC) under real life conditions. Prior to enrolling in this study, you were informed about the study details and you signed a form entitled "*Patient Information and Authorization for Use/Disclosure of Data*." By signing that form, you agreed that, for 10 years, certain companies and people would have access to see and use your personal health information from your original medical records and data resulting from your participation in the study. If you need a copy of this form, you may request a copy from your study doctor.

The purpose of this Addendum is to inform you:

- If you have any questions or notice anything different about your Humira® medication (if prescribed), contact your physician immediately for further instructions prior to taking your dose.
- And request your permission to share your study information with Janssen Biotech, Inc. as we have described below

AbbVie, the sponsor of this study, has contracted with Janssen Biotech, Inc. to share certain study results for developing, seeking regulatory approval for and commercializing by Janssen Biotech, Inc. of its medication named Simponi® or any other lawful purpose. If you agree, Janssen Biotech, Inc. will only receive your coded personal health information. Janssen Biotech, Inc. will not have access to your identifiable personal health information. Janssen Biotech, Inc. will use the personal coded health information for developing, seeking regulatory approval for and commercializing its medication named Simponi® or any other lawful purpose. Please take the time to read the following information carefully and discuss it with your doctor if you wish. You can ask as many questions as necessary.

The decision whether to share your coded personal health information with Janssen Biotech, Inc. is an optional part of the study. If you decide not to authorize us to share your coded personal health information with Janssen Biotech, Inc., then you can still continue to participate in the study.

SCHULMAN APPROVED
IRB #201407047
DATE: April 12, 2017

Patient Information and Authorization for Use/Disclosure of Data Addendum FOR PATIENTS ON IMM THERAPY AT ENROLLMENT

By checking the "*YES*" box below, you agree that your coded personal health information from the study will be shared with and used by Janssen Biotech, Inc. and anyone working on its behalf and the people and companies that it works with for purpose of developing, seeking regulatory approval for and commercializing of Janssen Biotech, Inc.'s medication named Simponi® or any other lawful purpose. Only coded personal health information collected after you check the "*YES*" box below and sign this addendum will be shared with and used by Janssen Biotech, Inc. and anyone working with or on behalf of Janssen Biotech, Inc. Once your coded personal health information leaves the study site it will no longer be covered by the HIPAA Privacy Rule. Janssen Biotech Inc. will ensure confidentiality of your data and will implement appropriate controls to ensure that such parties handle your personal health information in accordance with applicable data protection laws. By checking the "*YES*" box and signing this addendum, you agree to the transfer of your coded personal health information as described above.

Access to your coded personal health information begins as soon as you sign this form. This authorization expires fifty years after the date you sign this form, unless you revoke it sooner.

If you take back your permission to use or disclose your personal health information in the manner described in the "*Patient Information and Authorization for Use/Disclosure of Data*," any information that has already been collected at the time you take back your permission will be kept and, where the law allows, your coded personal health information, will continue to be used by Janssen Biotech, Inc. or other parties involved with the research. No new data will be collected about you after you withdraw your permission.

CONTACT FOR FURTHER INFORMATION:

You will receive a copy of this Addendum.

If you have any questions or concerns about any aspect of this study, you may obtain additional information at any time during the study by contacting the doctor listed on page one of this authorization form.

If you have any questions about your rights as a patient participating in a registry study, and/or concerns or complaints regarding this registry study, you should write to Schulman Institutional Review Board, Inc. 4445 Lake Forest Drive - Suite 300, Cincinnati, Ohio 45242, or call toll-free 1-888-557-2472 during business hours Monday - Friday 8:00 a.m. to 6:00 p.m. EST.

AUTHORIZATION

❒ **YES**, I voluntarily consent to the access and use of my coded personal health information by Janssen Biotech, Inc. as described in this Addendum.

❒ **NO, I DO NOT** consent to the access and use of my coded personal health information by Janssen Biotech, Inc. as described in this Addendum.

_____	_____
Subject Printed Name	Doctor Printed Name
_____	_____
Signature and Date	Signature and Date