**Informed consent for inclusion of the patient in the clinical study**

**Study title:** Immune response to SARS-CoV-2 vaccination in patients with autoimmune diseases treated with different types of immunosuppressive therapy  
**Acronym:** RESPONSE

**Institution:** 1st Department of Internal medicine, Department of Gastroenterology and Hepatology, Pilsen University Hospital, Alej Svobody 80, Pilsen, 304 60

**Pacient:** ................................................

**Identification number:**  ................................................

Dear Madam, dear Sir,

You have been approached to participate in the above-mentioned observational clinical study that addresses the issue of vaccination against SARS-CoV-2 in patients treated with immunosuppressive drugs. These patients are less likely to produce enough antibodies and other immune agents after vaccination and thus the vaccination may be less effective.

*Who can participate in the study?*

Patients with inflammatory bowel disease or autoimmune hepatitis who are in a non-active or mildly active phase in the disease course. In case of inflammatory bowel disease, the study may include patients who are not treated with immunosuppressive therapy, or who are treated with azathioprine alone, or in combination with anti-TNF alpha agent (infliximab, adalimumab). Finaly, healthy persons can also participate in the study in the control group protocol.

*What is the purpose of this study?*

The purpose of this study is to determine to which extent antibodies are formed after vaccination against SARS-CoV-2 in patients with inflammatory bowel disease or autoimmune hepatitis on different types of treatment.

*How does the study work?*

The study consists of a total of 3 visits in which you fill out a questionnaire and a blood sample is collected for detection of antibodies against SARS-CoV-2, total immunoglobulin G levels, and various other immunological parameters. The initial blood sample also includes examination of complete blood count and basic biochemistry to determine your disease activity, and examination of the level of 25-hydroxyvitamin D which plays an important role in your body's immune function. The initial visit and inclusion in the study must take place within 1 month before the start of SARS-CoV-2 vaccination, the second visit is scheduled 1 month after the end of vaccination and the third and last visit is scheduled 6 months after the end of vaccination. **Vaccination against SARS-CoV-2 is voluntary and it is performed as a part of the national vaccination program. Vaccination is not provided in the study.**

**Obtaining the blood sample**

**- Preparation**

You must be fasted for at least 6 hours before the collection of the blood sample.

**- Procedure**

Blood sampling is performed in accordance with the internal regulations of the University Hospital in Pilsen (SNL/DOS/SOP/039 Collection of venous blood). Medical material used is original and disposable and the patient is not at risk of any infection. Blood sampling is performed by a trained nurse in a separate room at the Dept. of Gastroenterology. A maximum of 20 mL of venous blood is collected. After collection, the site of injection is covered with a sterile swab and covered with a patch.

**- After the procedure, restrictions**

All usual activities can be performed after the procedure.

*How does the study benefit the patient?*

Thanks to this study, you will be able to find out for free how effective the SARS-CoV-2 vaccination was in terms of production of antibodies and cellular immunity. The results will always be available to you and your doctor. At the same time, you will find out for free the level of 25-hydroxyvitamin D and whether you need its substitution.

*What are potential risks associated with the study?*

The risks to the patient from this study are minimal. Obtaining three blood samples at the aforementioned intervals is not associated with the risk of complications and the questionnaire takes a maximum of 5 minutes to complete. No non-standard drugs are administered and no procedures are performed during this study. Blood samples may be temporarily stored in case of analytic failure and no tests other than those intended for the study will be performed.

**It will not be possible to identify your person from biological material and medical data provided for research purposes. Personal data will be handled in accordance with the valid laws of the Czech Republic on personal data protection**.

Participation in a clinical trial can be terminated at any time without affecting further treatment, and all further treatment is performed in a completely standard manner. Participation in this study is entirely voluntary and disagreement with participation will not adversely affect the patient-physician relationship or further treatment. If you have any further questions or concerns after reading this document, your questions can be answered at any time.

**PATIENT DECLARATION**

I have read the conditions of the study and the risks associated with it, and I agree to participate in the study.  
*I declare that I am interested in and I am planning the SARS-CoV-2 vaccination in the national vaccination program.*

I declare that I have been able to ask additional questions, which have been properly answered and that I fully understand the information and instructions and agree with the proposed procedure.

I have been informed that all data concerning my person are strictly confidential and will be treated in accordance with Act No. 110/2019 Coll., On the processing of personal data.

Patient's signature: ..............................................................................

Physician (healthcare professional) providing data and instructions: ………………… (name a signature)

In Pilsen, date and time: …..……… 2021 ……….