**PI**
Dr Fernando Rizzello

**Introduction**
You are invited to take part in the study "Effects of geraniol on the microbiota of patients with irritable bowel syndrome" promoted by the SSD for Chronic Inflammatory Bowel Diseases. Before deciding, it is important that you understand the reasons why the research will be conducted and what it will entail. Take all the time you need to read the following information carefully and discuss it with friends and family if you wish. This consent form may contain words that you do not understand. Ask the Investigator if something is not clear or if you wish to receive further information. Take the time necessary to decide whether or not to participate in the study.

**What is the purpose of this study and why was I chosen?**
You have been chosen to participate in this study because you are affected by Irritable Colon Syndrome (IBS). Several studies have documented that Irritable Colon Syndrome can occur following gastrointestinal bacterial infections, and that this pathology is associated with the presence of a low-grade inflammation of the mucosa and activation of the immune system. Also the gastrointestinal bacterial flora seems to play an important role in the genesis and in the physiopathological maintenance of IBS. Geraniol is a naturally occurring substance found in essential oils extracted from various plants, including geranium, which has demonstrated antibacterial capacity with greater selectivity for human microbiota bacteria defined as pathogens. The aim of this study is to evaluate, in patients with Irritable Bowel Syndrome, changes in the intestinal bacterial flora and the plasma inflammatory profile after taking a food supplement based on Geraniol.

**Am I obliged to participate?**
Participation in this study is voluntary. If you decide to participate you will be given this form of information to keep and you will be asked to sign an informed consent form. If you decide to participate you can still stop your participation in the study at any time without explanation. The decision to stop the study or the decision not to participate will not affect your right to receive the best possible treatment for your illness.

**What happens to me if I participate and what should I do?**
If after reading this form you decide to participate in the study, you will be asked to sign the Informed Consent form. The study does not require any change compared to the normal procedures for the treatment of your pathology during the next gastroenterologic visit that will be carried out, as provided for in the normal care path, we ask you to have a stool sample and to make a blood sample of about 3 ml to be analyzed for the purpose of the study. You will also be provided with a food supplement based on Geraniol and Soy Lecithin to be taken 2 times a day for 4 weeks. The supplement will be supplied in 150 mg capsules. The number of capsules to be taken will be determined based on your body weight, so as to reach a dosage of 8 mg / kg per day, using the following scheme:

Body weight Dose

48-59 Kg 3 capsules

60-74 Kg 4 capsules

75-89 Kg 5 capsules

90-104 Kg 6 capsules

During the following two gastroenterological visits that he will perform for the management of your pathology, we ask you to provide a stool sample and a blood sample of about 3 ml to be analyzed for the purpose of the study. The stool and blood samples will be analyzed anonymously by the molecular physiology laboratory of the Department of Biological, Geological and Environmental Sciences of the University of Bologna. All remaining material will be destroyed at the end of the trial.

**What are the side effects or risks if I participate?**
Geraniol has been recognized as a non-toxic substance for humans, and is now used as a food additive without restrictions. At the moment there are no known side effects related to the intake of this food supplement.

**What are the possible benefits?**
It is possible that you have no benefit to your disease from participating in this study, but your participation may help to understand the pathogenesis of Irritable Colon Syndrome and to improve the treatment of patients with the same disease in the future.

**What happens if new information becomes available?**
If new information about the study becomes available during the research, the Investigator or one of his collaborators will discuss it with you and will discuss together whether to continue your participation in the study.

**What happens if something goes wrong?**
If a problem occurs that requires the intervention of a doctor, you will be examined as soon as possible and receive the necessary treatment. In case of any damage related to your participation in the study will be refunded directly from the health facility where the trial takes place.

**What will happen to the results of the study?**
The results of this study can be presented at conferences or published; in any case, your name and other personal data that can identify you will not be included in any presentation or publication.

**Will I have to bear costs to participate in the study?**
The food supplement based on Geraniol will be provided free of charge. You will not have to incur additional costs to participate in this study. The study is carried out within the research activity of the SSD Chronic Inflammatory Bowel Diseases.

**Who evaluated the study?**
The Hospital Ethics Committee, in accordance with local and national laws, evaluated and approved this study.

**Contacts for further information**If you need further information, or if you have any problems, concerns or questions about the study, please contact the study doctor. The numbers to call are shown below

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If you decide to participate in this study, you will be given a copy of the Patient Information Sheet and the Informed Consent Form to take home and to keep as reference for the future.