

Informed Consent Form (ICF)

Official Title: The Crohn's Disease
Exclusion Diet With Early Dairy
Introduction Plus Partial Enteral
Nutrition (CD-EDEN) in Adult Patients
With Crohn's Disease

Unique Protocol ID:605/16-12-2021

(NCT ID not yet assigned)

Date: 24/08/2022

Participant ID number.....



**EVANGELISMOS GENERAL
HOSPITAL OF ATHENS**
Ispilantou 45, 10676 Athens – Tel: 213 2045035

Informed Consent Form

I

Resident in.....

Acknowledge and certify the following:

I agree to take part in the research project entitled “The Crohn's Disease Exclusion Diet With Early Dairy Introduction Plus Partial Enteral Nutrition (CD-EDEN) in Adult Patients With Crohn's Disease”, leaded by Dr. Gerasimos Mantzaris, Director of the Gastroenterology Department of the Evangelismos General Hospital of Athens

I understand that I will be informed of the study purposes and procedures before I decide to participate. I understand that my participation involves the implementation of certain biochemical analysis, to provide information regarding my nutritional status (to assess potential malnutrition or sarcopenia), as well as the disease progression. I am aware that my participation involves re-assessment of my nutritional status and disease monitoring at specific time points during and after the dietary intervention. I understand that I will be asked to complete questionnaires regarding my demographic characteristics, anthropometric and clinical parameters, dietary habits, physical activity and quality of life aspects.

I am aware that all study procedures will be held by experienced healthcare professionals and there is no health risk arising from my participation. I acknowledge that I had the opportunity to ask questions about the research project and how my information will be used. I have the right to be more extensively informed about any study procedure and method by the researchers. I know that my participation is voluntary and that I can choose to withdraw from the research at any point. Any information provided during the study will remain confidential and will be used exclusively and anonymized for the project.

I declare that I sign the Informed Consent Form for my voluntary participation in the study project.

Date: /..... / 202..

The volunteer
(Name and signature)

The researcher
(name and signature)