INFORMATION SHEET FOR PARTICIPATION IN AN OBSERVATIONAL STUDY AND DECLARATION OF CONSENT FOR CAPABLE SUBJECTS

18.05.2023 V.2.0

DERMATOLOGY COMPLEX OPERATING UNIT

SHEET

Dear Madam(s),

A medical-scientific research project entitled "Impact of clinical and psychological factors on treatment satisfaction in psoriatic patients on biological therapy**"** is planned at the Fondazione Policlinico Universitario A. Gemelli-IRCCS.

This research is national and monocentric in nature.

To carry out this research we need the collaboration and availability of people who, like you, meet the scientific requirements suitable for the evaluation that will be carried out. However, before you make the decision to accept or refuse to participate, please read this document carefully and take your time and ask us for clarification if you do not understand or need further clarification. In addition, if you wish, you can ask your family members or a trusted doctor for advice before deciding.

WHAT THE STUDY AIMS TO

The general objective of the study is to study demographic, clinical and psychological indices that have a major impact on the satisfaction of psoriatic patients on chronic therapy with a biological drug.

In particular, with the research that we present here, we intend to obtain data relating to your state of illness, the current therapy, your satisfaction with said therapy and your psychological profile.

WHAT YOUR PARTICIPATION IN THE STUDY ENTAILS

Your participation in the study will involve:

1. *Routine clinical data collection alone (e.g.* the age of onset and duration of disease, the presence of other concomitant pathologies, the residual location of the disease, the presence/absence of psoriatic arthritis, etc.)
2. *the administration of written questionnaires lasting about 10 minutes*

The study will last *twelve months* and 52 *patients* will participate in this research in this hospital.

WHAT ARE THE RISKS OF PARTICIPATING IN THE STUDY?

Participation in the study does not involve the performance of investigations or treatments other than those provided in normal clinical practice and therefore there will be no additional risks in the study compared to clinical practice.

WHAT ARE THE BENEFITS YOU WILL RECEIVE BY PARTICIPATING IN THE STUDY

No direct benefit to you is expected from participating in this study, but your participation will allow us to gain additional information about the condition you are suffering from.

WHAT HAPPENS IF YOU DECIDE NOT TO PARTICIPATE IN THE STUDY

You are free not to participate in the study. In this case, however, you will receive all the standard therapies provided for your pathology, without any penalty, and the doctors will continue to follow you with due care.

STUDY DISCONTINUATION

Your participation in this research program is completely voluntary and you may withdraw from the study at any time by notifying the Investigator. In this case, the data collected up to the time of collection *will not be* considered in the results in aggregated and anonymous form for the final analysis.

INFORMATION ABOUT THE RESULTS OF THE STUDY

If you so request, at the end of the study you may be informed of the results of the study in general and in particular those concerning you.

LEARN MORE

If you agree, it may be helpful to inform your GP about your participation in this study.

For further information and communications during the study, the following staff will be available:
Dr. Giacomo Caldarola e-mail: giacomo.caldarola@unicatt.it Tel: 063015-5284 Dr. Gennaro Marco Falco, e-mail: gennaromarco.falco@guest.policlinicogemelli.it Tel: 063015-5284

The study protocol proposed to you has been drafted in accordance with the current revisions of the European Union's Standards of Good Clinical Practice and the World Medical Association's Declaration of Helsinki on Clinical Trials involving Human Subjects and has been approved by the Ethics Committee of this facility. You may report any fact you deem appropriate to highlight, in relation to the experimentation that concerns you, to the Ethics Committee of this structure.

DECLARATION OF CONSENT

DECLARE

1. to have received from the Doctor _____ explanations regarding the request for participation in the research in question, as reported in the section of which I have been given a copy before, forming part of this consent, a copy of which was given to me on _____

2. that the nature, purposes, procedures, expected benefits, risks and drawbacks have been clearly explained to me and understood;

3. that you have had the opportunity to ask any questions to the study investigator and that you have received satisfactory answers;

4. that you have had sufficient time to reflect on the information received;

5. that you have had sufficient time to discuss it with third parties;

6. to be aware that the search may be interrupted at any time;

7. that I have been informed that the results of the study will be made known to the scientific community, protecting my identity according to current privacy legislation;

8. to be aware that any choice expressed in this consent form may be revoked at any time and without any justification;

9. that you have received a copy of this consent form.

Date	Patient's signature
Date	Signature of the doctor who informed the patient

In this case:

I , the undersigned..... ..... I testify that Dr. ..... has fully explained to Mr. .....
the characteristics of the experimental study in question, as reported in the attached information sheet, and that the same, having had the opportunity to ask all the questions he deemed necessary, freely agreed to join the study.

Date..... Signature of the independent witness .....

Date..... Signature of the physician who gave the information to the patient .....