REGIONE PUGLIA
AZIENDA OSPEDALIERO UNIVERSITARIA
Ospedale Policlinico Consorziale – Bari
U.O. Complessa di ENDOCRINOLOGIA

UNIVERSITÀ DEGLI STUDI DI BARI ALDO MORO
Dipartimento di Medicina di Precisione e Rigenerativa e Area Jonica
Sezione di Medicina Interna, Endocrinologia, Andrologia e Malattie Metaboliche

Direttore: Prof. **Francesco Giorgino**

INFORMED CONSENT ON CONSERVATION OF BIOLOGICAL MATERIAL

Version 1 of 27.12.2022

I, the undersigned . . . . . .

Born in . . . . . .

Resident in . . . . . .

Province . . . . . ZIP/CAP . . . . . .

Address . . . . . .

Phone number . . . . . .

After being informed that:

- The biological material retrieved can be conserved at the laboratory
- The biological material retrieved may be utilized for further investigations at exclusive research purpose, never for direct profit.
- As per the law D.L. N° 196/03, anonymity and privacy will be guaranteed, and privacy on the origin of the sample and on genetic data obtained will be maintained.
- I will express the will not to be informed on the results of further investigations (as per art. 10 comma 2 of the Convenzione sui diritti dell'Uomo e sulla Biomedicina – Oviedo 4 Aprile 1997, ratified in the law 28 Marzo 2001, n° 145).
- The suitability of the sample will be kept at any cost; nevertheless, the Center declines the responsibility for any damage o accidents that may happen.
- The genetic data acquired may be conserved and possibly used for the sole aim of research.
- In any moment I will be able to communicate a change of mind about what I declared; in which case, the sample and the accompaning data will be erased and will not be used for further research.

Telefoni & Fax:

Direzione	0805478689
Segreteria Direzione	0805592308
Segreteria Clinica	0805594174
Fax	0805478783

DIVISIONE CLINICA

Medicheria	0805592314
Sala Medici	0805592495
Reparti Degenza	0805592688
Prenotazioni	0805592490

DAY HOSPITAL

Prenotazioni	0805592490

LABORATORI

Diagnostica	0805592640
Ricerca	0805594186

AMBULATORI
Malattie Endocrine (Tiroide, Paratiroidi, Surrene, Ipofisi)
Nutrizione Clinica
Diabete Mellito
Andrologia Medica
Prenotazioni 0805592156

Indirizzo:
Piazza Giulio Cesare, 11 – Padiglione "V. Chini"
70124 BARI

E-mail:
istituto.segreteria@endo.uniba.it

REGIONE PUGLIA
AZIENDA OSPEDALIERO UNIVERSITARIA
Ospedale Policlinico Consorziale – Bari
U.O. Complessa di ENDOCRINOLOGIA

UNIVERSITÀ DEGLI STUDI DI BARI ALDO MORO
Dipartimento di Medicina di Precisione e Rigenerativa e Area Jonica
Sezione di Medicina Interna, Endocrinologia, Andrologia e Malattie Metaboliche

Direttore: Prof. **Francesco Giorgino**

DECLARES:

Authorize	Not authorize	the biological material conservation
Authorize	Not authorize	the exclusive use of materal for diagnosis and/or research
Authorize	Not authorize	the conservation of genetic data and the use for research purposes
Want	Do not want	to be informed on results about health coming from these studies and researches

Date _____ Signature _____

The undersigned, Prof./Dr. . . . . , guarantees the respect of the previous declarations.
Any future test will be done after authorization by the Ethics Committee.

Date _____ Signature _____

Telefoni & Fax:

Direzione	0805478689
Segreteria Direzione	0805592308
Segreteria Clinica	0805594174
Fax	0805478783

DIVISIONE CLINICA	
Medicheria	0805592314
Sala Medici	0805592495
Reparti Degenza	0805592688
Prenotazioni	0805592490

DAY HOSPITAL	
Prenotazioni	0805592490
LABORATORI	
Diagnostica	0805592640
Ricerca	0805594186

AMBULATORI
Malattie Endocrine (Tiroide, Paratiroidi, Surrene, Ipofisi)
Nutrizione Clinica
Diabete Mellito
Andrologia Medica
Prenotazioni 0805592156

Indirizzo:
Piazza Giulio Cesare, 11 – Padiglione "V. Chini"
70124 BARI

E-mail:
istituto.segreteria@endo.uniba.it

REGIONE PUGLIA
AZIENDA OSPEDALIERO UNIVERSITARIA
Ospedale Policlinico Consorziale – Bari
U.O. Complessa di ENDOCRINOLOGIA

UNIVERSITÀ DEGLI STUDI DI BARI ALDO MORO
Dipartimento di Medicina di Precisione e Rigenerativa e Area Jonica
Sezione di Medicina Interna, Endocrinologia, Andrologia e Malattie Metaboliche

Direttore: Prof. **Francesco Giorgino**

INFORMATION FOR THE PATIENT AND INFORMED CONSENT

Version 1 of 27/12/2022

TITLE: Relationship Between Parameters of Glycemic Control and Irisin Levels in Patients With Diabetes Mellitus Type 2 and Sarcopenic Obesity or Non-sarcopenic Obesity

PRINCIPAL INVESTIGATOR: Prof. Francesco Giorgino

PATIENT NAME: _____

Dear Sir/Madame,
We invite you to participate in a study on biological material about the evaluation of blood irisin levels.
The study is done at Azienda Ospedaliero-Universitaria Policlinico "Consorziale" in Bari. The study includes a venous sampling from the antecubital vein for research purposes.

PURPOSE OF THE STUDY

The study proposes to understand if, and in which magnitude, body composition and glycemic control are correlated to irisin levels.
It is known, indeed, that irisin levels are lower in people with fewer muscle mass (condition known as sarcopenia) and in patients with Type 2 Diabetes Mellitus.
Finding a significative correlation may, in the future, provide basis for studies in which irisin might be used as a therapy to increase the muscle mass and/or to improve the glycemic control. If this, then, will demonstrate effective, we will have yet another weapon to improve the wellness of patients affected by sarcopenia and Type 2 Diabetes Mellitus.

REGIONE PUGLIA
AZIENDA OSPEDALIERO UNIVERSITARIA
Ospedale Policlinico Consorziale – Bari
U.O. Complessa di ENDOCRINOLOGIA

UNIVERSITÀ DEGLI STUDI DI BARI ALDO MORO
Dipartimento di Medicina di Precisione e Rigenerativa e Area Jonica
Sezione di Medicina Interna, Endocrinologia, Andrologia e Malattie Metaboliche

Direttore: Prof. **Francesco Giorgino**

PATIENT PARTICIPATION

The study will be conducted on the about 3000 patients affected by Type 2 Diabetes Mellitus that are routinely visited every year in the Diabetology clinic of the Policlinico di Bari.
Your participation in the study consists in your consent to the venous sampling from the antecubital vein, in the use of the sample for the study in object, and in the use of the data that are routinely detected to check your glycemic status and other cardiovascular risk factors (biochemical exams and anthropometric data).
These data will be utilized for a statistic analysis that will allow to obtain the wanted information, without interfering with your privacy. The data that will be retrieved will be known to your doctor and to the authorized personnel; any other person will not be able to know your name due to a cyber protection mechanism of the database.

RESPONSIBILITY AND PROCEDURES

If you will participate in this study, the above data from the visit(s) that you routinely undergo will be reported on a cyber record and on your outpatient record. Your doctor and the authorized personnel will be the only ones to have access to your personal data (name, surname, place and date of birth, place of residence and phone number) on the cyber record, and they will as well be the only ones with access to your outpatient record.

RISKS CONNECTED TO THE VENOUS SAMPLING

The physical risks and the disturbances related to the blood sampling are identical to the ones of any type of venipuncture, that is the possibility of small local bruises and local irritation

POSSIBLE BENEFITS

You will not have any direct benefit from participating in this study. Nevertheless, this study might contribute to increase our knowledge about Type 2 Diabetes Mellitus and favour the development of therapeutic patient-specific strategies.

COSTS

You will not incur in any adjunctive payment because the visits, the laboratory analyses and the instrumental analyses done for the study are the same that you undergo for routine visits, according to good clinical practice, while experiments done on the blood sample will be carried out at our Laboratory of biomedical research in Endocrinology and Metabolism of the Department of Precision and Regenerative Medicine and Jonic Area (DiMePRe-J) and the relative costs will be on the university funds

REGIONE PUGLIA
AZIENDA OSPEDALIERO UNIVERSITARIA
Ospedale Policlinico Consorziale – Bari
U.O. Complessa di ENDOCRINOLOGIA

UNIVERSITÀ DEGLI STUDI DI BARI ALDO MORO
Dipartimento di Medicina di Precisione e Rigenerativa e Area Jonica
Sezione di Medicina Interna, Endocrinologia, Andrologia e Malattie Metaboliche

Direttore: Prof. **Francesco Giorgino**

of the above mentioned Department, Internal Medicine, Endocrinology, Andrology and Metabolic Diseases section.

INSURANCE

As there will not be any deviation, due to the study, from normal procedures that you undergo in your periodic visits, no insurance is needed.

ALTERNATIVES TO PARTECIPATION

You are not forced to participate in this study to receive an optimal treatment for your pathology.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your participation in this study is completely voluntary. You can decide not to be involved or, if you decide to participate, you can later decide to withdraw, without the need of explanations. Accepting to participate in this study doesn't force you to participate in future studies. If you decide not to participate or to withdraw you will not be penalized in any way, nor you will lose any of the benefits you have the right to.

QUESTIONS

You are encouraged to ask questions. If you have any doubt about the study, we encourage your to speak about it to your doctos who, if needed, will get you in touch with the study head, Prof. Francesco Giorgino. Please don't sign this module unless you had the opportunity to ask questions and obtain satisfying answers. If you accept to participate in this study you will receive a copy of this informed consent module signed for your private documentation.

Date:_____

Name and surname of the investigator: _____

The investigator: _____

REGIONE PUGLIA
AZIENDA OSPEDALIERO UNIVERSITARIA
Ospedale Policlinico Consorziale – Bari
U.O. Complessa di ENDOCRINOLOGIA

UNIVERSITÀ DEGLI STUDI DI BARI ALDO MORO
Dipartimento di Medicina di Precisione e Rigenerativa e Area Jonica
Sezione di Medicina Interna, Endocrinologia, Andrologia e Malattie Metaboliche

Direttore: Prof. **Francesco Giorgino**

TITLE: Relationship Between Parameters of Glycemic Control and Irisin Levels in Patients With Diabetes Mellitus Type 2 and Sarcopenic Obesity or Non-sarcopenic Obesity

INFORMED CONSENT

I read and understood the information in this module of informed consent (or they have been read to me). By signing this module I certify that this study has been explained to me and Dr_____ answered to my questions. I accept to participate in the study. By signing this consent I don't give up any of my rights as a patient in a study on human biological material. I acknowledge that participation is completely voluntary and that I can withdraw from the study at any moment without having to explain myself and without osing my benefits.

According to the law DLgv 196/03, I acccept that personal data about my pathology collected for the above mentioned study will be saved as encoded by regulatory authorities for scientific analysis and eventual publications
I consent that representatives form regulatory authorities have confidential access to my medical data, to ensure correct management of the study.

Name of the patient: _____

Signature of the patient: _____

Date: _____

Certification of the person who explained the informed consent

I discussed the above points with the patient. It is my opinion that the patient understands the risks, benefits and the procedures of this study.

Signature of the person who explains the informed consent

_____

Date _____

----------To utilize if applicable ----------

If this consent module is read to the patient because he can't read, it is required for an impartial witness not involved in the study or with the investigator to sign the following declaration:

I confirm that the information in this module of informed consent and any other written information have been accurately explained and apparently understood by the patient. The patient freely agrees to participate in this study.

Signature of an impartial witness _____
Date _____