**Model A**

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**FACT SHEET**

**AND DECLARATION OF CONSENT**

**for an adult patient able to personally consent**

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**Part 1**

Dear Patient,

1) This Institute of Hospitalization and Treatment of a Scientific Nature, Policlinico San Donato promotes a study that aims to identify biomarkers in patients with acute coronary artery syndrome undergoing coronary angioplasty.
The title of the study is: RNA as prognostic biomarkers in patients with acute coronary syndrome.
This research takes place exclusively in this structure.
In order to carry out this research, we need the cooperation and availability of people who, like you, meet the scientific requirements for the evaluation that will be carried out. We therefore propose you to participate in this research on which you have already had detailed information from the doctor responsible dr. Luca Testa.
However, before you make the decision to accept or refuse to participate, please read these pages carefully, taking all the time you need, and ask for clarification if you did not understand or need further clarification. In addition, if he so wishes, he may, before making his decision, seek advice from his family members or from his trusted doctor.

2) This research aims to identify predictive biomarkers (mRNAs) of ventricular dysfunction in patients with acute coronary syndrome undergoing coronary angioplasty, as a clinical indication.

3) If the study decides to participate, it shall include the following:
Additional blood samples (one tube of 3 ml and two of 4 ml) before the coronary angioplasty procedure, 24 hours after the procedure, 6 months and 12 months. These blood samples will be used for the analysis necessary for the identification of biomarkers.
Data will also be collected from echocardiograms performed as per clinical practice prior to the coronary angioplasty procedure, 24 hours after the procedure, 6 months and 12 months.
378 patients will participate in this research at this Hospital who will be chosen among all those who are affected by the same disease of which you are affected.
The study foresees that the samples will be collected, processed and stored at the BioCor biobank located at the San Donato Polyclinic for the time necessary to carry out the research activities. The samples will then be transferred to the BIOREP biobank (via Olgettina 60, c/o Ospedale San Raffaele-DIBIT2) for long-term storage. To this end, you will be asked to express or deny your consent to the storage of samples in biobanks.
If you refuse to consent to the storage of samples in the biobank, your biological material will be destroyed after the analysis provided for in the protocol.
4) The study provides for the following control surveys:
• Blood samples before the coronary angioplasty procedure, 24 hours after the procedure, 6 months and 12 months (specifically performed by the protocol).
• Echocardiograms before the coronary angioplasty procedure, 24 hours after the procedure, 6 months and 12 months (clinical routine).

5) No direct benefits for you can be expected from your participation in this study.

However, the results obtained from this research will help to deepen knowledge about the disease; the information that will be obtained with this study may bring future benefits to you and other people with your own health problems.

6) Participation in the study does not involve risks.

7) Any damage resulting from participation in the trial will be covered by the IRCCS Policlinico San Donato.

8) If the patient is a pregnant woman, he will not be able to participate in this study.

9) You are free/to not participate in the study. In this case you will receive, however, the standard therapies provided for the pathology from which you are affected and the doctors will continue to follow it with due care.

10) Your participation in this research programme is completely voluntary and you may withdraw from the study at any time.
If data becomes available that may influence the decision to continue the study, it will be promptly informed/a.

11)The protocol of the study that has been proposed to you has been drawn up in compliance with the Standards of Good Clinical Practice of the European Union and the current revision of the Declaration of Helsinki and has been approved by the Ethics Committee of this structure to which you can report any facts it considers appropriate to highlight, concerning the experimentation that concerns you, by sending correspondence to the President of the Committee: President of the Ethics Committee - Ospedale San Raffaele - Via Olgettina, 60, 20132 Milan.

For further information and communications during the study you can contact the following staff: Dr. Luca Testa 02/52774980

**DECLARATION OF CONSENT**

[ this statement must be signed and personally dated by the patient and the doctor who conducted the discussion on informed consent]

I undersigned ……

I have received from the doctor ……..

full explanations of the request for participation in the experimental study in question, as reported in the information sheet annexed hereto, a copy of which I received sufficiently in advance.
I also declare that I have been able to discuss these explanations, that I have asked all the questions that I considered necessary and that I have received satisfactory answers, and that I have had the opportunity to inquire about the details of the study with a person I trust.
I agree, therefore, freely to participate in the trial, having understood the meaning of the request and having understood the risks and benefits involved and I consent to my attending physician being informed of my participation in the study. I am aware of my right to withdraw from the trial at any time.
I have also been informed of my right to free access to the documentation relating to the trial (insurance, clinical-scientific, pharmacotherapeutic) and the evaluation expressed by the Ethics Committee.

Date..... Patient's signature ……..……..

Date..... Signature of the doctor who informed the patient ……
……..

[If the patient is unable to read or sign, an independent witness from the experimenter and sponsor must be present during the entire discussion of informed consent. The witness shall personally sign and date the informed declaration of consent after the form itself and any other written information has been read and explained to the subject and the subject has given verbal consent to the participation in the study].

In this case:

I, the undersigned .... ……
…….
…….
the characteristics of the experimental study in question, as reported in the information sheet attached hereto, and that the same, having had the opportunity to ask all the questions it deemed necessary, freely agreed to join the study.

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

Date..... Signature of the doctor who gave the information to the patient …….

***Part 2***

***INFORMATIVE***
***PURSUANT TO ART. 13 OF THE GENERAL DATA PROTECTION REGULATION (EU) 2016/679***
***("REGULATION" OR "GDPR")***

Data controller:

- ("IRCCS") Policlinico San Donato, s.p.a., based in San Donato Milanese (MI), in via Morandi n.30, as "Sponsor", reachable at the e-mail address:
luca.testa@grupposandonato.it;
("Data Controller")

-The Sponsor has appointed Data Protection Officer (henceforth, "Data Protection Officer" or "DPO") available at the e-mail address RPD.PSD@grupposandonato.it;

Description and purpose of the study
The description and purpose of the study have been reported in the previous paragraphs.

**Purpose of Processing**
The IRCCS Policlinico San Donato, s.p.a., Sponsor of the research project that has been described to you, in accordance with the responsibilities provided by the norms of good clinical practice (D.L. 211/2003),
is the owner of the processing operations related to the carrying out of scientific research and will process your common personal data (name, surname, date of birth, etc.) and particulars (data relating to your health, your origin, your lifestyles, your sexual life)biological data, only after its prior, specific and explicit consent exclusively for the implementation of the clinical trial and only to the extent that they are indispensable in relation to the objective of the study itself and for the purposes of supervision.
For this purpose the data indicated will be collected by the Sponsor.
The basis of legitimacy for the processing of your data for this purpose is your explicit consent pursuant to Articles 6.(1)(a) and 9(2)(a) GDPR. The provision of your data for this purpose is optional, however, being essential to the conduct of the research project, its possible refusal will not allow you to participate.
You can revoke ex art. 7 of the GDPR the consent given for the aforementioned purposes at any time without providing any justification; in this case the biological samples related to you, if still identifiable, will be completely destroyed, and in this case no further data concerning you will be collected, without prejudice to the use of any data already collected to determine, without altering, the results of the research.

**Processing methods and nature of data**
The doctor who will follow you during the trial will identify you with a code (for example: ab0001) that does not allow you to directly trace your identity: the data that will be collected during the trial, with the exception of your name, will be recorded, processed and stored together with this code, your date of birth, gender, weight, stature and all clinical data relating to your state of health
Only the doctor and authorized subjects can link this code to your Name.
In order to guarantee confidentiality, even the test tubes containing your biological samples will be labelled with specific codes that show the code attributed to you.

The processing of the data will therefore take place in a manner that makes it possible to unambiguously ascertain the identity of the subject to whom the biological material is taken for the analysis, but that allow the identification of patients only for the time necessary through the use of a code. Any appropriate means will be adopted to identify the data subject only in case of need, separating identification data where possible.

Biological samples will be stored, transported and used in ways that also guarantee their quality, integrity, availability and traceability.
The above data will be collected, managed and stored, both in paper and electronic format and in any case processed in accordance with the legislation on the processing of personal data, including the applicable provisions and authorisations issued by the Data Protection Authority.
More information is available at the Data Controller or at the DPO at the addresses indicated above.

**Scope of data circulation**
Your participation in the study implies that, in accordance with the legislation on clinical trials of medicinal products, the staff duly authorized by the Promoter pursuant to art. 29 of the GDPR, the Ethics Committee and the Italian and foreign health authorities, as independent data controllers, will be able to know the data concerning you, also contained in your original clinical documentation, in such a way as to guarantee the confidentiality of your identity.
With regard to the possible transfer of Data to Third Countries, the Data Controller informs that the processing will take place in any case according to one of the methods permitted by current law, such as your consent, the adoption of Standard Clauses approved by the European Commission, the selection of subjects belonging to international programs for the free movement of data or operating in countries considered safe by the European Commission. More information is available at the Data Controller or at the DPO at the addresses indicated above.
Your data will be disclosed only in a strictly anonymous form at scientific conferences or through scientific publications or statistics.

**Conservation**
The Personal Data will be stored only for the time necessary for the purposes for which they are collected, respecting the principle of minimization referred to in Article 5(1)(c) of the GDPR as well as the legal obligations to which the Data Controller is bound.
Your related samples will be stored for a maximum duration equal to the time needed to carry out the research activities, after which they will be destroyed. Such biological samples will not be transferred to third parties not involved in the trial, nor will they be used for research purposes other than those described in this document without your new consent.
More information is available at the Data Controller or at the DPO at the addresses indicated above.

**Exercise of privacy rights**
You may, pursuant to and under the effects of Articles. 15 and ss. of the GDPR, access your personal data, verify its content, origin, accuracy, location (also in relation to third countries where the data are located and/ or to the subjects to whom the data can be disclosed), request a copy, integration, update, rectification and, in the cases provided for by the law in force, cancellation, transformation in anonymous form, the limitation, data portability, the revocation of the consent given pursuant to art. 7 of the GDPR; as well as lodge a complaint with the competent supervisory authority pursuant to Article 77 of the GDPR (Data Protection Authority).

We also inform you that you may object to the processing of your personal data pursuant to art. 21 of the Regulation.

The modification of the original data may have a significant effect on the results of the study, so that in case of exercise of rights involving variation/integration of the recorded data, the changes requested may be recorded and recorded in the margin of the original data without modifying the original data.

You may discontinue your participation in the study at any time without giving any justification; in this case, the biological samples related to you will be completely destroyed.
No further data concerning you will be collected, without prejudice to the use of any data already collected to determine, without altering, the results of the research.

To exercise your privacy rights, you can contact the DPO or the Data Controller at the addresses indicated above.

**Consent**

I, the undersigned (name and surname) ……..... born in ……..... /..... /... /... tax code_____ resident in (municipality)..... (Prov.) _____ _____ _____ _____ ……

aware of the criminal sanctions provided for by art. 76 of D.P.R. 445/2000 for the hypothesis of falsehood in acts and false statements

☐ for myself

☐ or as an independent witness*

[* If the patient is unable to read or sign, an independent witness from the investigator and sponsor must be present during the entire discussion of informed consent. The witness shall personally sign and date the informed declaration of consent after the form itself and any other written information has been read and explained to the subject and the subject has given verbal consent to the participation in the study].

Of (name and surname) _____..... born in _____ _____ _____ …….
street (address) ……

Read and understood the information referred to in Art. 13 of EU Regulation 2016/679 "The Regulation or GDPR" and aware of the right to withdraw consent at any time pursuant to art. 7 of the GDPR, without prejudice to the lawfulness of processing based on consent before revocation:

☐ I agree ☐ I do not agree

The processing of my common and particular personal data for research purposes but within the limits and in the manner indicated in the information.

Date..... Place...;

Signing …….....
(Extended and legible signature)