AFFIRMO

Privacy policy provided pursuant to art. 13 and consent pursuant to art. 6 and 9 of EU Regulation no. 679 of 2016

Title of study:	**Atrial Fibrillation integrated approach in FraIl, multimoRbid and polyMedicated Older people (AFFIRMO)**
Study code:	**HCF-K23**
Promoter of the study:	**Fondazione per il Tuo cuore - HCF Onlus**
Funding:	**European Union's Horizon 2020 research and innovation programme - Grant agreement No. 899871**
Participating centre:	.....
Principal Investigator:	.....

Fondazione per il Tuo cuore – HCF Onlus (hereinafter, the "**Foundation**" or the "**Data Controller**"), as Promoter of the "AFFIRMO" study (hereinafter, "**AFFIRMO Study**"), pursuant to and for the purposes of art. 13 of the EU Regulation no. 679 of 2016 (hereinafter, the "**GDPR**"), and subsequent amendments and additions, collects and subsequently processes the personal data of the participants to the AFFIRMO Study (hereinafter, the "**Data Subject**"), including those falling under the "special categories" referred to art. 9 of the GDPR, as Data Controller.

1. Purpose and methods of the processing.

Your (Data subject) personal data are collected by the Participating Center (independent Data Controller of the data concerning health, for therapeutic purposes) where you are treated and processed within the institutional activity of the Foundation, with the following scientific purposes:

1. the registration and your relative participation in the AFFIRMO Study;
2. the fulfilment of specific obligations provided by the law, regulation or Community legislation closely related to participation to the AFFIRMO Study.

In order to protect the collective health, further statistical or research surveys are possible. In this case, the surveys are required by Health Authority, and therefore it won't be necessary to ask you for your specific consent.

The processing of personal data takes place, under the authority of the Data Controller, by persons specifically appointed, designated and instructed to the process of personal data pursuant to art. 2-*quaterdecies* of Legislative Decree no. 196 of 30 June 2003, as amended by Legislative Decree no. 101 of 10 August 2018, (hereinafter, the "**Italian Privacy Code**") and art. 29 of the GDPR, using manual, computerized or telematic tools, with logic closely related to the purposes and in any case to ensure the confidentiality and security of personal data.

The Data Controller, during your personal data processing through electronic methods, may also use an APP or equivalent tools.

The data, processed also with electronic instruments, will be disseminated only in strictly anonymous form, for example through scientific publications, statistics and at scientific conferences. Your participation in the AFFIRMO Study implies that, in compliance with the regulations on clinical trials of medicines, the staff of the Foundation (as Promoter) or of the external companies that carry out the monitoring and verification of the Study on behalf of the Promoter, as well as the Ethics Committee and the Italian and foreign Health Authorities of the other participating countries (Bulgaria, Denmark, Romania, Serbia, Spain), will be able to access and review your data, also contained in the original clinical documentation, in such a way as to guarantee the confidentiality of your identity.
The Data Controller, in accordance with the responsibilities provided by the rules of good clinical practice, will process your personal data and in particular those relating to your health, exclusively in relation to the

implementation of the AFFIRMO Study and only to the extent that they are essential in relation to the objectives set by the same.

2. Categories of personal data processed.

The doctor/researcher who follows you in the AFFIRMO Study will identify you with a Study Code: your data, collected during the trial, with the exception of personally-identifying information like your name or address, will be transmitted to the Promoter of the AFFIRMO Study, recorded, processed and stored together with a code, age, sex, weight, height and data concerning your health.
Only the doctor and the designated subjects will be able to connect the code assigned to you to your name.
As mentioned, your personal data acquired for the AFFIRMO Study include those falling under the special categories of data referred into art. 9 of the GDPR, such as:

- age, gender and ethnicity;
- health and clinical conditions including clinical history;
- treatments and response to it;
- biological samples, such as blood and tissues, and the results obtained from their analysis;
- medical images (e.g. scans and X-rays, and the results of their evaluation).

3. Mandatory or optional nature of data provision and consequences of a possible refusal, consent of the Data Subject.

With reference to the objective referred into paragraph 1, point 1. the provision of data is optional, but the refusal to provide the same only makes impossible for you to participate in the AFFIRMO Study. Therefore, the lawfulness for the treatment of the data is your express consent, pursuant to art. 6, paragraph 1, letter a) and the art. 9, paragraph 2, letter a) of the GDPR.

Since all the required consents are optional, your decision not to participate in the AFFIRMO Study does not imply any consequence on its diagnostic and therapeutic process.

4. Subjects or categories of subjects to whom the personal data can be given and scope of communication.

In relation to the purposes of the processing indicated above, and within the limits strictly pertinent to the same, in order to include you in the AFFIRMO Study, your personal data will be communicated in Italy, within or outside the EU, to the following subjects:
(i) the structures and/or external companies of which the Data Controller avails himself and which act on his behalf, in charge of carrying out activities strictly connected with, instrumental to or consequent to the registration and your subsequent participation in the AFFIRMO Study (for example, institutions and research institutes, associations and other public and private bodies with research purposes, etc.);
(ii) the public authority, where required by law or at its request;
(iii) external consultants, if not designated in writing as Data Processors.

If your personal data belonging to the special categories referred into art. 9 of the GDPR, collected for research purposes within the AFFIRMO Study, are communicated or transferred to third parties who do not participate jointly in the aforementioned Study, the information and samples may be communicated only in such a way that it is not possible to trace your identity, may be used only for the pursuit of research objectives directly related to those for which they were originally collected and clearly indicated in writing in the request for data and/or samples. In this case, the requesting third parties will not be able to use the information and/or samples for different purposes than those indicated in the request, and will not be able to disclose or transfer them further to other third parties.

The subjects indicated above, to whom your personal data will or may be communicated (as they are not designated in writing as Data Processors), will process the personal data in their capacity as independent Data Controllers in accordance with the GDPR, fully independent, being unrelated to the original processing carried out by the Foundation.
A detailed and constantly updated list of these subjects, with an indication of their respective offices, is always available at the registered office of the Foundation.

5. Transfer of coded data to other countries outside the EU.

Your coded data (as specified in the information provided to you and in the consent form) may be transferred or processed in countries outside the EU. This could happen also in countries where the level of data protection has not been confirmed as adequate by the EU; in such cases, the Data Controller shall ensure that appropriate security measures are taken to safeguard your rights of confidentiality. In the event of any doubt you may freely contact the Data Controller.

6. Controller, Processors and Data Protection Officer.

As Promoter of the AFFIRMO Study, the Data Controller of your personal data exclusively for scientific research purposes is the Fondazione per il Tuo cuore - HCF Onlus, with registered office in Florence, Via La Marmora n. 36, telephone +39 055/5101367, fax +39 055/5101360 and email segreteria@periltuocuore.it.

The updated list of the Data Processors, where designated, can be given on your request.

The identification data of the Data Protection Officer (pursuant to art. 37 of the GDPR) appointed by the Foundation can be found at the following link https://www.periltuocuore.it/dpo

7. Your Rights.

Art. 15 and following of the GDPR give you, as the Data Subject, the right to obtain:

- the confirmation of the existence or not of personal data concerning you, even if not yet recorded, and their communication in an intelligible form; however, in order to safeguard the scientific integrity of the AFFIRMO Study, it may not be possible to access to some of those data before the conclusion of the same;
- the indication of the origin of the personal data, the purposes and methods of the processing, the logic applied in case of processing carried out with the help of electronic instruments, the identification details of the Data Controller;
- updating, rectification, integration, cancellation, transformation into anonymous form or blocking of data processed unlawfully - including data no longer required to be kept or used for the purposes for which the data were collected or subsequently processed - certification that such operations have been notified, as also related to their content, to those to whom the data were disclosed or disseminated, unless this requirement proves impossible or involves a manifestly disproportionate to the protected right.

You, as the Data Subject, also have the right:

- to interrupt at any time and without providing any justification your participation in the AFFIRMO Study; 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 them, the results of the scientific research in question;
- to object, in whole or in part, for legitimate reasons, the processing of your personal data, even if pertinent to the purpose of collection;
- request the correction of your data, if they are incorrect or incomplete; during the evaluation of such request, you have the right to limit the processing of the data concerning yourself;
- request the transfer of data concerning you to you or to another person in a commonly used format;
- to make a complaint to the Data Protection Authority in the cases provided by the GDPR.

In order to know the detailed and constantly updated list of the subjects to whom your personal data may be disclosed and to exercise the rights as per art. 15 and following of the GDPR, you may contact the Data Controller at the addresses indicated in paragraph 6, in the manner set out in art. 12 of the GDPR and within the limits set out in art. 2-*undecies* of the Italian Privacy Code.

8. Duration of data processing.

Your coded personal data will be kept for at least 25 (twenty-five) years after the conclusion of the AFFIRMO Study, or for a different period, if necessary due to legal requirements.

CONSENT

pursuant to art. 6 and 9 of GDPR

Having read the above privacy policy, I, as the Data Subject:

☐ give consent

☐ deny consent

to using my data for the purpose of registration and participation in the AFFIRMO Study, in accordance with the terms and conditions indicated above.

For acknowledgement and acceptance

_____	_____	___/___/___
Patient's first name/surname in block capitals	Patient's signature	Date

_____	_____	___/___/___
First name/surname of the impartial witness	Signature of the impartial witness	Date

(Only if the patient is not able to write. The witness should be able to read and write, not be an employee of the trial center, not be the patient's spouse or first-degree relative and not be involved in the clinical trial in any role.)

_____	_____	___/___/___
Name and surname of researcher in block letters	Signature of researcher	Date

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 899871