REGIONE AUTONOMA FRIULI VENEZIA GIULIA
ISTITUTO DI RICOVERO E CURA A CARATTERE SCIENTIFICO
Burlo Garofolo di Trieste
BURLO

IMAGINE EURO Improving MAternal Newborn carE

WHO Collaborating Center for Maternal and Child Health Trieste Italy

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INFORMATION SHEET FOR THE TREATMENT OF COLLECTED DATA

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(pursuant to Article 13 of EU Regulation 679/2016, and D.Lgs. 196/2003, as amended by D.Lgs. 101/2018)

TITLE: IMAGINE EURO (Improving MAternal Newborn carE In the EURO Region): Survey on maternal and newborn health service preparedness, quality and resilience, among countries of the WHO European Region, at different phases of the COVID-19 pandemic

PROMOTER: WHO Collaborating Center for Maternal and Child Health, Burlo Garofolo Hospital, Trieste, Italy, leading a group of maternal and child health researchers and health advocates from 10 European countries at least.

PRINCIPAL INVESTIGATOR (PI): Dr Marzia Lazzerini, Director of WHO Collaborating Center - IRCCS Burlo Trieste, Italy

CONTACTS OF THE RESPONSIBLE EXPERIMENTATOR: E-mail: marzia.lazzerini@burlo.trieste.it

PERIOD OF CONSERVATION: Collected data will be kept until the purposes of the Project are reached, within the limits established by the laws that regulate the matter.

DATA PROTECTION OFFICER (DPO): With regards to the data provided, the interested party can contact the DPO appointed by the holder of the Institute for Maternal and Child Health Burlo Garofolo, Ing. Michele Bava, at the following email: dpo@burlo.trieste.it.

PROCESSING OF DATA AND INFORMED CONSENT REQUEST

Dear Madam,
with this form we invite you to participate in the non-profit international research study entitled IMAgiNE EURO promoted by the WHO Collaborating Center, of the IRCCS Burlo Garofolo, Trieste, Director Dr. Marzia Lazzerini. The principal investigator (PI) of the research study is Dr. Dr. Marzia Lazzerini (E-mail: marzia.lazzerini@burlo.trieste.it), medical director at the aforementioned WHO Collaborating Centre, assisted by Dr. Emanuelle Pessa Valente (emanuelle.pessavalente@burlo.trieste.it,) and Dr. Benedetta Covi (benedetta.covi@burlo.trieste.it,).
Participation in the international research project involves the compilation of an online questionnaire in voluntary and anonymous form. The participant will have adequate time to reflect and ask questions for clarification before consent to participate.
The person involved in the study will have the right to withdraw their consent at any time without having to provide any justification without losing any right or benefit.

Objective of the study:
First of all, we thank you for the time you dedicate to us.
We ask your cooperation as this study has been developed in coordination with WHO Regional Office for Europe (EURO) and other partners and ultimately aims at making available and diffuse data that can help improving the quality of maternal and neonatal health services in the Region. Collecting data on the quality of essential MN health services across different countries within the WHO European Region will help addressing specific gaps and planning coordinate response to improve quality of MN care and improve MN health outcomes.
The purpose of the study is to:
1. Record, analyze, describe and diffuse data on quality of essential MN health services, as measured both from health workers and women perspectives, across different countries within the WHO European Region, at different stages of the COVID-19 pandemic.
2. Develop tools and methods to measure the quality of MN health care across different countries and settings
3. Establish and consolidate, through the activities on the other objectives, a research network

The information will be collected by an online survey and the data will be reported and disseminated only in strictly anonymous form, through the use of reports, statistics and / or publications ensuring the protection of data and identity.

Participants' rights (including the right to withdraw consent to participate in the study at any time)
You will be guaranteed sufficient time for reflection and consultation, and for asking questions for clarification; participation in the study will be voluntary. At any time, you will have the opportunity to withdraw without giving any reasons. Participation in the study is free: the study does not foresee costs due to its observational nature.

Reference legislation
Pursuant to European REGULATION No. 679/2016, c.d. "GDPR n. 679/2016 "- General Data Protection Regulation" Protection of individuals with regard to the processing of collected data, as well as the free movement of such data "as well as of Legislative Decree no. 196/2003 "Code regarding the protection of personal data" (so-called Privacy Code) as amended by Legislative Decree no. 101/2018 "Provisions for the adaptation of national legislation to the provisions of Regulation (EU) no. 679/2016 of the

European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of collected data, as well as on the free movement of such data and which repeals Directive 95/46 / EC (general regulation on the data protection) "and any subsequent further amendments and additions.

Other information
We also inform you that the proposed international research study protocol has been drafted in compliance with the European Union for Good Clinical Practice Rules and the current revision of the Helsinki Declaration and has been approved by the Friuli Venezia Giulia Ethics Committee, by the competent Health Authorities or by the institutions delegated by these.

Principal investigator
For any doubt, question or request for details concerning the study, please contact: Dr. Marzia Lazzerini at the Collaborating Center of the WHO, IRCCS Burlo Garofolo.
E-mail: marzia.lazzerini@burlo.trieste.it

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(pursuant to Article 13 of EU Regulation 679/2016, and D.Lgs. 196/2003, as amended by D.Lgs. 101/2018)

This Notice is made pursuant to and for the purposes of art. 13 of EU Regulation 679/2016 (hereinafter "GDPR"), concerning the protection of individuals with regard to the processing of collected data.

Data controllers
Dr. Francesca Tosolini, appointed Commissioner of the IRCCS Burlo Garofolo of Trieste. Contacts: e-mail: direzione.generale@burlo.trieste.it.

Contacts of the Data Protection Officer (DPO)
With regards to the data provided, the interested party can contact the DPO appointed by the holder of the I.R.C.C.S maternal infant treatment Burlo Garofolo, Dr. Michele Bava, at the following email: dpo@burlo.trieste.it

Purposes
The data controller, for the areas of its competence and, in accordance with the responsibilities provided for by the legislation on the processing of collected data, will process collected data only to the extent that they are indispensable in relation to the objective of the study.

Legal basis of the processing
The legal basis for processing your data is your consent. The processing of collected data is essential for the conduct of the study: the refusal to grant them will not allow you to participate.

Recipients or any categories of recipients of collected data
Collected and processed data by the Promoter, may be transmitted anonymously to:
- Ethics Committee;
- Regulatory Authorities;

Possible extra-EU data transfer and warranty tools used
If necessary, for the purposes of the research study, your data may also be transferred to countries not belonging to the European Union upon the release of your consent. Data will be transferred in compliance with the provisions of EU Regulation 2016/679.

Period of conservation
Collected data will be kept until the purposes of the Project are reached, within the limits established by the laws that regulate the matter.

Nature of the data
All data will be collected anonymously.

Treatment modalities
All data collected will be used by the WHO CC for the exclusive purposes of research study. They may be disclosed in scientific

articles, but only anonymously and in aggregated form. The socio-demographic data requested will be used only for statistical purposes for subgroup analysis and presented anonymously as aggregated data. Data will be treated in accordance with the guidelines for the processing of personal data adopted by The Italian Data Protection Authority regulated subsequently by the Personal Data Protection Code (Legislative Decree No. 196 of 30 June 2003) as amended by Legislative Decree No. 101 of 10 August 2018, which also established that the Italian DPA is the supervisory authority responsible for monitoring application of the General Data Protection Regulation (pursuant to Article 51 of Regulation No. 2016/679).

You are free to choose whether or not to participate in the study.
If you decide to participate, you must tick the "YES" box under the statement "I have read and understand the above consent form, and, by selecting “Yes” below, I declare I am 18 years of age or older and I indicate my willingness to voluntarily take part in the study.” at the beginning of the online questionnaire.
Participation in the project is voluntary and involves completing an online questionnaire in completely anonymous form and can be interrupted at any time without indicating the reasons and will not entail any negative consequence for women and her baby with respect to the care received / agreed upon with the healthcare professional.
Each participant is free to request clarifications on the data collection procedure and on any aspect of research to the study manager, Dr. Marzia Lazzerini (Email: marzia.lazzerini@burlo.trieste.it).
The data, processed using electronic or electronic means, will be subject to automated decision-making processes, including profiling (processing of data with electronic tools). The data will be disseminated only in strictly anonymous form, for example through scientific publications, statistics and scientific conferences.

Rights of the interested parties
Your participation in this international research study is voluntary.
You may refuse to take part in the study or exit the online questionnaire at any time without penalty. Since the data will be collected completely anonymously, recorded sequentially and disseminated anonymously and aggregated, we cannot delete the recorded data since, once saved, they will no longer be traceable.
The data will be kept, in the same way, for the time of the study.
You can use the following rights at any time, compatibly with the research purpose of this study:
- right to object to the processing of your data;
- right to the portability of your data.
- right to refuse participation in this research if you wish to do so
- right to stop participating in the survey at any time that you wish without your care received / agreed upon with the healthcare professional being affected.

Be free to request clarifications on the data collection procedures and on any aspect of this research from the study manager (Dr. Marzia Lazzerini, marzia.lazzerini@burlo.trieste.it).

It may also use the right to lodge a complaint with the Guarantor for the protection of collected data according to the methods indicated on the website http://www.garanteprivacy.it.
Contacts: Privacy Guarantir, Piazza di Monte Citorio n. 121, 00186 Rome - Tel. 06 696771 - Fax 06 696773785 - e-mail garante@gpdp.it.

Giving consent to participate at the international research study, you declare that you have read the foregoing information. You have had the opportunity to ask questions about it and any questions. You consent voluntarily to be a participant in this study.

This proposal has been reviewed and approved by Institutional Review Board dell'IRCCS Burlo Garofolo, which is a committee whose task it is to make sure that research participants are protected from harm.