INFORMATION DOCUMENT AND DECLARATION OF CONSENT for the healthy volunteer

Dear Madam/Sir

1) Participants are invited to take part in a research on the evaluation of the effect of shift working on sleep quality, circadian rhythm of activity levels and motor control. The research is entitled: "Effects of shift work on health: assessment of the sleep quality, motor control and cardiovascular risk." This research is monocentric, that is, it takes place exclusively in this structure. The person in charge of the study is Prof. Fabio Esposito.

2) The study aims to identify the type of shift with less impact on the health state of nurse staff. To this purpose the effects of shift working on the quality of sleep, on the circadian rhythm of activity levels and on motor control will be evaluated.

3) If participants decide to be involved in the study, the experimental design of this research will provide the following:

Chronobiological evaluation:
- Compilation of questionnaires Horne-Ostberg Morningness-Eveningness Questionnaire (MEQ);
- Actigraphic monitoring for the assessment of sleep quality and circadian activity-rest rhythm; this analysis consists of wearing an actigraph, a device similar to a clock that will record the movements done during sleep and during waking activities.

Evaluation levels of physical activity and cardiovascular risk:
- Compilation of the International Physical Activity Questionnaire (IPAQ) questionnaires;
- Compilation of the QRISK2-2017 questionnaires;
- Monitoring with a heart rate monitor (R-R mode) for hearth rate variability analysis.

Evaluation of the mood profile:
- Compilation of the Profile of Mood States questionnaires (POMS).

If participants agree to participate in this study, they will be referred to a first visit to verify that their conditions meet the criteria required by the study.

Once participants enter the study, their participations will consist of:
- Completing the questionnaires described above;
- Wearing the actigraph as described above;
- Undergoing evaluation with a heart rate monitor and surface electromyography as described above.

Participation in the trial will not entail any expense.

4) The study foresees the carrying out of the investigations described in the previous paragraph.
In particular, the collaboration has different deadlines depending on the habitual shift schedule: the participants will be divided into 3 groups according to the shift schedule provided by the department to which they belong:
- GROUP 1: total duration 5 days, 24-hour shifts;
- GROUP 2: total duration 10 days, 24-hour shifts;

- GROUP 3: diurnal shifts only.

The investigations described above will have the following deadlines:

Preliminary evaluations (for all GROUPS)
- MEQ questionnaire administration: duration approximately 10 minutes;
- IPAQ questionnaire administration: duration 10 minutes;
- Questionnaire QRISK2-2017: duration 5 minutes.

At the beginning and after 8 days
- Motor control evaluations: duration 10 minutes;
- Hearth rate variability analysis: duration 10 minutes;
- POMS questionnaire administration: duration 3 minutes.

5) As healthy volunteers, participants will not receive any direct benefit from participating in this study, but the results will provide useful information to be able to reason on any revaluation of the shift system by making any changes.

6) Since no invasive measures are planned within the study, participation in the study does not expose to particular risks.

7) It should be noted that, given the non-invasiveness of the proposed procedures, no *ad hoc*-insurance policy has been activated for the study.

8) In case of pregnancy (ascertained by self-declaration) or breastfeeding, participants will not have to participate in this trial.

9) Participants are free to not participate in the study.

10) The adherence to this research program is completely voluntary and participants can withdraw from the study at any time: experimentation may be interrupted whether undesirable side effects should occur. In this case, the participants will be promptly informed and treated in the appropriate way for the resolution of the adverse events occurred.
Should data become available that could influence the decision to continue the study in question, it will be promptly informed.

11) The protocol of the proposed study was drafted in accordance with the European Union Clinical Practice Rules and the current revision of the Helsinki Declaration and was approved by the Ethics Committee of this structure to which participants can report any fact deems it appropriate to highlight, in relation to the experimentation that concerns the participants, by directing the correspondence to the Chairman of the Committee: Chairman of the Ethics Committee - San Raffaele Hospital - Via Olgettina, 60, 20132 Milano. [Point 5.24 of the guidelines for the Ethics Committees: "Direct access to the Ethics Committee must be available to experimentation subjects who are dissatisfied .. It is the responsibility of the investigator to inform (of this possibility) the subjects of experimentation"].

12) For further information and communications during the study, participants can contact the following staff member: Dr. Pasqualino d'Aloia. Phone: 0266214704

DECLARATION OF CONSENT

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

I, the undersigned .....

I declare to have received from the doctor .... exhaustive explanations regarding the request to participate in the experimental study in question as a healthy volunteer, as reported in the information sheet attached, a copy of which was delivered to me sufficiently in advance.
I also declare that I have been able to discuss these explanations, to ask all the questions I have deemed necessary and to have received satisfactory answers, as well as to have had the opportunity to inform me about the details of the study with a person of my trust.
I accept, therefore, in full and absolute freedom to participate in the trial, having fully understood the meaning of the request, including the risks and that, in particular, I will not receive any direct benefit and consent to my attending physician being informed of my participation in the study. I am aware of my right to withdraw from experimentation at any time.
I have also been informed of my right to have free access to the documentation related to the trial (insurance, clinical-scientific, drug-therapeutic) and to the evaluation expressed by the Ethics Committee.

Date ..... Signature of the healthy volunteer ....

Date ..... Signature of the doctor who informed the healthy volunteer .....

DISCLOSURE
pursuant to article 13 of the D.Lgs.196 / 03
(Code regarding the protection of personal data)

Data controllers and related purposes:
The Institute of Hospitalization and Care with a Scientific Character Galeazzi Orthopedic Institute based in Milan, in via R. Galeazzi n.4 (hereinafter the Experimentation Center) that commissioned the study entitled "Effects of health check: assessment of the quality of sleep, motor control and cardiovascular risk ", in accordance with the responsibilities established by the rules of good clinical practice (DL 211/2003), will process participants' personal data - in particular those on health and, only to the extent that they are indispensable in relation to the objective of the Study, other data relating to participant's origin and lifestyles - exclusively according to the realization of the Study.

The processing of personal data is essential for the conduct of the study; any refusal will not allow the participation in the trial.

Nature of data:
The investigator who will follow the participants during the trial will identify them with a code: the data that will be collected during the study (i.e. date of birth, sex, body mass, stature and all the clinical data concerning health), with the exception of the name, will be recorded, processed and stored together with this code. Only the investigators can link this code to the participant name.

Methods of Processing and Communication to Third Parties
The above data will be collected, managed and stored, both in paper and electronic format, by the Experimentation Center and, in the form indicated in the preceding paragraph - transmitted also to countries outside the European Union that do not guarantee an adequate level of protection of personal data (indicate the identification details of any third party companies outside the European Union).

Data will be disseminated only in a strictly anonymous form at scientific meetings or through scientific or statistical publications.

The participation in the Study implies that, in accordance with the legislation on clinical trials of medicines, the staff of the Institute or of the external companies specifically appointed performs the monitoring and verification of the Study. Furthermore, the Italian and foreign Ethics Committee and the Health Authorities will be able to know the data concerning the participant, which are also contained in the original clinical documentation, with the aim of evaluating the correctness and accuracy of the data collected, adopting, in any case, all the precautions to ensure the necessary confidentiality of participants' identity.

Exercise of rights
Pursuant to and for the purposes of Article 7 of Legislative Decree 196/03, addressing directly to the IRCCS Galeazzi Orthopedic Institute, participants have the right to obtain:

- Confirmation of the existence or not of personal data concerning them, even if not yet recorded, and their communication in an intelligible form.
- Updating, rectification or, when interested, integration of data;
- Cancellation, transformation into anonymous form or blocking of data processed unlawfully, including data whose retention is unnecessary for the purposes for which the data were collected or subsequently processed;

- The attestation that the operations referred to in letters b) and c) have been brought to the attention, also with regard to their content, of those to whom the data have been communicated or disseminated, except in the case where such fulfillment is it proves impossible or involves a use of means manifestly disproportionate to the protected right.

Participants have the right to object, in whole or in part, for legitimate reasons to the processing of personal data concerning themself, even if pertinent to the purpose of collection.

Participants may interrupt the participation in the study at any time and without giving any justification; in this case, no further data will be collected that concerns it without prejudice to the use of those already collected to determine, without altering, the results of the research.

For further information and communications during the study, participants can contact the following staff member:
Dr. Pasqualino d'Aloia. Phone: 0266214704

CONSENT

Having read the above information and having understood the entire content, by signing this agreement I consent to the processing of my personal data and its transfer outside the European Union for the purposes of the research within the limits and with the methods indicated in the information.

Date _____

NAME AND SURNAME OF THE INTERESTED PARTY _____
(in block letters)

_____
(signature)