INFORMATION AND CONSENT FORM FOR THE PARTICIPATION OF ADULTS IN CLINICAL TRIALS

Where the study is carried out

The experimentation will involve people recruited between people applying to the study and visitors of the exhibition "*Painting affections: sacred painting in Ferrara between the 16th and 17th centuries*", which will be set up at the Estense Castle in Ferrara from 26 January to 26 December 2019.

Title of the research:

NEVArt: Neuroestethics of the Art Vision

Coordination

The CIAS (*Centre for Pollution of Environments with High Sterility*), an Interdepartmental Laboratory of the University of Ferrara, is the Project Coordinator, in collaboration with the Institute of Neurosciences of the CNR of Parma and the Laboratory of Neuroaesthetics of CESPEB (*Centre for Studies on History of Biomedical Thought*) of Milan.

Promoter and Sponsor or any other sources of funding

The research is funded by the CIAS Research Centre and by the Consorzio Futuro in Ricerca.

Local coordinator

The coordination of the research is entrusted to prof. Sante Mazzacane, from the CIAS Interdepartmental Research Centre. The CIAS work staff includes: Maddalena Coccagna, Arianna Vivarelli, Matteo Bisi, Antonella Volta, Luca Lanzoni, Silvia Cesari, Giuseppe Camillo Santangelo, Davide Orlando, Gabriele Martini.
The research takes place in collaboration with prof. Vittorio A. Sironi of the Laboratory of Neuroaesthetics of the CESPEB of the Bicocca of Milan, with researchers from the State University of Milan (Raffaella Folgieri, Annalisa Banzi) and with Eng. Pietro Avanzini of the Institute of Neurosciences of the CNR of Parma (staff: Maddalena Fabbri Destro, Giovanni Vecchiato)

Dear Madam,
on the occurrence of this art exhibition, we intend to develop the experimental study NEVArt, aiming to involve a large number of participants, on field and not in a lab, to have a frame of people's physiological, neurological and cognitive emotional reaction while watching an artwork. According to this purpose, it will be valuable the help from people also very different in nationality, age, gender, education, customary to art exhibits, etc.
For this reason, we would need your cooperation.
Participation in a clinical trial is an important decision. Before your resolution to accept or refuse to apply, please read this information carefully, taking your time to understand. You may ask us for details if something is not clear or if you need any further information.

Why we're searching for applicants?

We propose you to take part to the research because you can provide us with fundamental data to identify, in a scientific way, the neurophysiological, cognitive and emotional response of people when viewing an artwork, in particular about how much it may be pleasant or not.
You, together with all those who will participate in NEVArt, will provide us with a statistically relevant data to give strength to our analyses, confirming or not the international background in this field.

What is this study designed for?

We decided to carry out this study because, thanks to the technological availability of portable and non-invasive tools and sensors, we can now collect on field and not only in the lab, real-time information on how people react to artworks and, in general, to different "artistic" pictures.
The study aims to provide, on a broad statistical basis, a framework of people's physiological neurological and cognitive emotional reaction when facing an artwork (painting, sculpture, architectural building, etc.), analysing persons of different ages, gender, education, customary to art exhibitions, etc. (read more about the research project).
The participants will all be registered through a blind code and his/her personal data will be collected and store separately and in no way correlated to the data coming from the field trial.

What does participation in this study entail and what are your responsibilities as an applicant?
According to the design of this study, there are no restrictions about the use of drugs or food because of the trial, nor any restrictions and obligations to take drugs or food for participants. Teratogenic events are not conceivable (that is, they can cause damage to the foetus during a pregnancy). However, for statistical reasons, the participation of pregnant women is not expected. There are no special post-study provisions; participants who will ask it in the enrolment form, will receive an informative newsletter on the scientific results of NEVArt.
The participation in the study is free of charge and will not be rewarded in any way.
Thanks to the invaluable help of the Municipality of Ferrara, the research participants may fully see, free of charge, the exhibition "*Dipingere gli affetti - Painting the affections*".

What are the risks or drawbacks of participating in this study?

Taking part in the research does not involve risks, as the sensors that will be applied are light and do not cause pain. These tools include:

- an eye tracker (similar to a frame of glasses, without lenses, therefore usable also with any glasses), that record a real-time video of what you are looking at how your eyes move along the painting;
- an EEG meter, that is a device to put in the head, which records the electrical activity of the brain;
- a set of skin sensors: ECG (measures the heart bit using bipolar surface electrodes), GSR (detects the electrical resistance of the skin).

The use of this set of devices allows a wide framework of feelings and emotions when looking at paintings and to analyse if there will be any kind of correlation between different kind of signals.
This information can lead to further scientific developments, not only to improve the exhibitions criteria and the way of communicating art or to promote art on a wider public, but also to expand our knowledge about the way of collecting this kind of data though field studies.
Compared to the traditional visit to an exhibition, a little patience is required, because the trial preparation need at least:

- 10’ to read and sign of the informed consent (even if you have the opportunity to read it online before asking to apply) and for the compilation of a short set of general data using the same PC tablet provided to complete the trial; your data will be used anonymously;
- 10’ to apply and check all the sensors, verifying both that you are comfortable wearing them and that all signals will be stored properly in our computer;
- 30/45’ to watch paintings selected for the trial and to assess your experience, one to one, through a survey that you will find on the tablet;
- 5’ remove the sensors.

At the end of the trial you can visit again all the exhibition, not just the selected pictures.

There are possible benefits of participating in this study?

This study will have no benefits or negative effects on your person; however, it will help us to better understand some cognitive processes and therefore also to study or consolidate international hypotheses on how we can intervene both to improve the dissemination of artworks and to apply our technical skills using portable equipment to other fields of interest.

Participation in the study does not involve costs and will not be rewarded in any way; however, thanks to the collaboration with the Municipality of Ferrara and the Management of the Estense Castle, you have a free entrance ticket to the castle and to the exhibition "Painting the affections: the sacred painting in Ferrara between the '500 and the '600", which was set up at the Estense Castle in Ferrara from 26th January to 26th December 2019.

What are the alternatives when participating in this study?

Since this is not a study that presupposes medical benefits, your decision not to participate will only diminish the chances for us to reach the minimum number of experimental data we have set when designing the study.

Is it possible not to participate or change my mind?

Participation in this study is voluntary. You can refuse to participate in the study or withdraw from the study at any time, without having to give any explanation and without any penalty or negative consequence. Your refusal to participate or the decision to stop participating in the study in no way will affect the assistance you receive, which will still be the best available.

We have decided to make all the research documentation available online and you can take your time before asking to participate. At the time of your application you will be asked for a period, day of the week or preferred time; we will try to take this into account, but when we send you a possible date for the test, you can of course decide not to participate.

How to enrol in the study?

Enrolment, which is on a voluntary basis, takes place by completing our application form, available online to the project webpages (see: www.cias-ferrara.it).

Once you have an appointment, if for different reasons you will not be able to participate, just let us know (as soon as possible) to be able to recruit other applicants; however, no liability will be attributed to you if this is not the case.

Any new information that could influence your decision to continue or not to participate in the trial will be communicated to you as soon as possible. The same for any possible interruption or suspension of the study.

How does the experimentation take place?

You will wear a set of sensors, which may be of a different type according on the choices and requirements of the scientific protocol developed by the researchers. You will be then attended by a researcher during the visit of a selection of paintings. At the end of the vision of each of them, you have to fill out a really short questionnaire using a PC tablet. The entire trial takes about 40 minutes.

Who to contact for more information and during the study?

The coordination of the research is entrusted to CIAS, whose director is prof. Sante Mazzacane. The Centre provided a secretariat to manage the recruitment of NEVArt research participants, entrusted to the arch. Maddalena Coccagna, who will be at your disposal for any further information, including your rights, how to receive details about the study, etc. You can write to the project secretariat at this address: nevart@unife.it or call this number +39.0532.293658.

Access to the original clinical documentation

Direct access to your original documentation will be allowed to the monitoring or verification personnel, the Ethics Committee and the regulatory authorities for a verification of the study procedures and/or data, without violating the confidentiality rules, to the extent permitted by law and by applicable regulations.
By signing the informed consent form, you authorize this access.
Any documents that can identify you (your demand for application and the signed consensus agreement) will be kept confidential and, to the extent permitted by applicable laws and/or regulations, will not be made publicly available. If the results of the study will be published, your identity will remain secret.
As regards the processing of your personal data, please read the related information.

Information about the results of the study

If interested and if you ask for it, at the end of the trial you can receive more information about the general results of the study. The protocol of this study and this information sheet have been arranged in accordance with the Rules of Good Clinical Practice and the Declaration of Helsinki and have been approved by the Ethics Committee of the Wide Area Emilia Centro (CE-AVEC) on 10.03.2019.

NEVArt: NEUROESTETHICS OF THE ART VISION

CIAS | University of Ferrara

INFORMED CONSENT FORM

I, the undersigned .....

Born in..... the .....

Living in....., street....., n .....

phone....., e-mail .....

HEREBY DECLARE

- to received comprehensive explanations regarding my application in the study, in particular on the aims and procedures;
- to had the opportunity to ask questions and I received adequate answers;
- to read and understood the information sheet that was delivered to me sufficiently in advance;
- to understood that participation is voluntary, and that I will be able to withdraw from the study at any time, without giving explanations and without any prejudice for my future assistance in any way;
- to be aware that, if I withdraw my consent, the data collected before the withdrawal of consent will be used by the researcher.

As a result of these statements:

I freely accept to participate in the study

Name and surname of the participant .....

Date..... Signature.....

Name and surname of the person obtaining consent.....

Date..... Signature.....

Note:

1 copy for the participants;

1 copy for the Responsible for data processing