

# DECLARATION OF COMPLIANCE WITH THE PRINCIPLES OF THE DECLARATION OF HELSINKI

**Title study :** [ Name full study ]

**Study identification number :** [ Study identification number attributed ]

**Start date Study start date :** [ Start date] study ]

**location research :** [ Location or INSTITUTION where it takes place the study ]

**Principal Investigator :** [ Name] full name of the principal investigator ]

---

## 1. Consent informed of the participants

- **Participation agreement:** All the participants were informed completely and clear about purpose the study, the nature of the procedures involved, the risks and benefits possible. They were informed that contribution is VOLUNTARY and that they can withdraw in any time during the study, without A affect care physician or other rights.
  - **Consent form:** All the participants signed consent form informed before starting contribution in study. The forms were editor in a language accessible , and the participants had the opportunity to put question to fully understand What GET INVOLVED participation .
- 

## 2. Protection PRIVACY and data PERSONAL

- **Privacy:** information PERSONAL and Participants ' medical conditions are treated with strict PRIVACY and will not be disclosed without their express consent, in except for cases regulated by law. All DATES will be anonymized or pseudonymized there where is possible.
  - **Storing data:** data will be kept in a form that ensures their protection, and access will be limited to people authorized involved in research.
- 

## 3. Evaluation RISK and benefits

- **Evaluation risks:** All RISKS POTENTIAL for participants were evaluated and minimized as much as possible. These risks are described clear in consent form informed, and the participants were informed about POTENTIAL adverse effects.

- **Benefits:** Participants are informed about the benefits possible research outcomes, which may include advancing knowledge scientific, but not guaranteed BENEFITS direct for participant.
- 

#### 4. Approval ethics

- **Ethics Committee :** The study was approved by an independent ethics committee ( or an ethics committee institutional ), according to regulations in force . Evaluation ethics was accomplished for A ensure that the study respect PRINCIPLES ETHICAL stated in The Helsinki Declaration.
  - **Endorsement ethics:** [Date and Ethics committee approval number], [ Name ethics committee].
- 

#### 5. Rights participant

- **Withdrawal from the study:** The participants were informed that I can leave the study anytime, without suffering ANY consequence negative on their medical treatment or A OTHER rights.
  - **Question and clarifications:** The participants had access to information additional during studied and they had the possibility of address any study -related questions in which they are involved.
- 

#### 6. Responsibility researchers

- **IMPLEMENTATION OF protective measures:** Researchers are engaged saddle Wall all ACTIONS REQUIRED to protect health and safety participant and to respect norms ETHICAL and legal, according to the principles The Declaration of Helsinki.
  - **reports results:** Researchers will publish the results studied in a transparent manner and responsible, ensuring that they will not be omitted information important and that they will not address CONCLUSIONS unfounded on the basis of DATES collected.
- 

#### 7. Declaration compliance with the principles The Declaration of Helsinki

By the signature of May down , we confirm that this study was HELD in accordance with the principles ETHICAL fundamentally stated in The Helsinki Declaration of the Association World Medical , as well as with all regulation ETHICAL and link Helpful enforce Surveys What GET INVOLVED subjects human .

---

**Signature to the principal investigator :**

[ Name complete , signature and date]

**Signature the ethics coordinator (if his case):**

[ Name complete, signature and date]

**Signature ethics committee :**

[ Signature and approval from the ethics committee ]

---

This structured model can be adapted and personalized for each study, in depending on requirements ETHICAL and proceeding specific to the institution or ethics committee What YOU supervise.