Human Observational Study Protocol

#####

##### **Project in which the study is included:**

**Project reference:**

**Principal Investigator:**

**Research centre(s) involved:**

Universidad Politécnica de Cartagena (UPCT), Cartagena, Spain

xxxxx

**1. Protocol Title**

**2. Justification of the study**

**3. Objectives**

**4. Safety of participants**

**5. Study Design**

* 1. **Summary of the study**

**5.2 Participation and recruitment of participants**

**5.3 Study population**

**6. Inclusion and exclusion criteria**

**6.1 Inclusion criteria**

**6.2 Exclusion Criteria**

**7. Study procedure**

**7.1 Sample collection/surveys**

**7.2 Withdrawal of study participants**

**9. Changes during the study**

**10. Obligation of the researcher**

**12. Participant Consent**

*Approval will be obtained from the UPCT CEI for written informed consent prior to use. This consent form will comply with all regulations governing the protection of human subjects. Each subject will sign and date an informed consent form to participate in the study. A signed copy of the consent form will be given to the subject and a signed copy will be retained by the investigator in the participants' file.*

*Participants can withdraw from the study at any time without prejudice. In addition, the investigator may remove participants from the study if it is in the best interest of the participant. The reason for the withdrawals of study participants will be documented in the participant's file.*

**13. Data collection**

The investigator is responsible for ensuring that all study records are complete and maintained in accordance with the study protocol. If for any reason the participant does not complete the study, an explanation will be recorded in the file.

**14. Confidentiality**

**15. Funding**

The costs associated with the execution of the study will be covered by

**16. Dissemination Policy**

*The data derived from the study will be the property of the UPCT. The data will be disseminated in the form of scientific presentations/abstracts and published in a scientific journal. Authors will acknowledge funding sources in all publications. Participants will also be informed about the results of the study.*