

**ISS-EC STUDY PROPOSAL SUMMARY FORM**

**GENERAL INFORMATION**

**1. Title of the study:**

**2. Principal investigator:**

Surname:

Name:

Affiliation:

Contacts: (e-mail; phone; city; country)

**3. Coordinator (for multicentre studies)**

Name Surname:

Affiliation:

Contacts: (e-mail; phone; località)

**4. Sponsor/s \***

*\** ***“Sponsor”*** *definition according to EU Regulation No. 536/2014 (Article 2 point 14) is: "* *“an individual, company, institution or organization which takes responsibility for the initiation, management and for setting up the financing of the clinical trial.”*

**5. Centres participating in the study:**

* One centre
* More centres

*Please report the detailed list of the centres in an attached document*

**6. Study duration (mos):**

**7. Geographic coverage:**

* Local/Regional
* National
* European
* International

**STUDY DESIGN**

**8. Study synopsis:**

*Please briefly describe (max. 3,000 characters) the rational with the expected primary and secondary objectives. If the request concerns the evaluation of a project workpackage/task, please specify how this activity fits in the general context.*

**9. Type of study:**

* Observational
* Experimental
* Methodological

**10. In case of an experimental study please specify if it is:**

* Interventional with drugs
* Interventional with medical device(s) or different biomedical technology (es)
* Other typology of intervention (i.e.: occupational therapy, psychotherapy, etc.)
* *In vitro* study

**11. In case of experimental study please specify the typology of the study (multiple answers possible):**

* Randomised
* Blind
* With placebo

**12. Observation length:**

* Transversal
* Longitudinal

**13. Type of observation (multiple answers possible):**

* Prospective
* Retrospective

**14. The study population includes (multiple answers possible):**

* Adult participants/patients
* Healthy volunteers
* Families/control groups
* Minors
* Patients not able to express their informed consent in absence of their legal representative/guardian/tutor

**15. Inclusion/exclusion criteria:**

**16. Sample size:**

**PERSONAL DATA**

**17. Does the study require personal data processing \*?**

*\*Definition of «****processing****» according to the European Regulation 2016/679: any operation or set of operations which is performed on personal data or on sets of personal*

*data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making.*

*available, alignment or combination, restriction, erasure or destruction;*

*\*Definition of «****Personal data****» according to the European Regulation 2016/679*: “*personal data” means any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person;*

* Yes
* No

**18. Will an informed consent be obtained from study participants/patients ?**

* Yes
* No, because the consent obtained previously is sufficiently exhaustive
* No, because it would involve a disproportionate effort
* I don’t know

**19. In case the acquisition of a new informed consent involves a disproportionate effort, is it considered to give some information to study participants/patients (i.e. through a website, newspapers, brochures, etc.)?**

* Yes
* No

**20. Ways to process personal data within the study:**

* Data collected anonymously at the origin
* Irreversible anonymisation (definitive removal of every link between personal data and code)
* Pseudonymisation (replacement of personal data with a code)
* Identifiable data

**21. Was the information notice on personal data approved by the Data Protection Officer (DPO) of the Institution/Centre/Organization?**

* Yes
* No
* Aninformation notice on personal data is not provided for this study

**RISKS AND BENEFITS**

**22. Expected benefits:**

* Direct benefits for the participant
* Benefits for people with a similar disease
* Benefits for science and for the community

**23. Main risks or discomforts for the participant:**

* Minimal risk for physical harm (i.e. a bruise after a blood draw)
* More than a minimal risk for physical harm (i.e. an adverse drug reaction)
* Need of biological material draw /clinical tests (biopsy, blood, X-RAY, ECG, etc.)
* Psychological distress (i.e. surveys administration)
* Need of more medical examinations after the first one
* Not applicable

**24. Insurance coverage of the study:**

According to the Italian Decree n. 211/2003 and the EU Reg. n. 536/2014 the sponsor and the investigator have a civil liability and a consequent obligation to compensate for any damage suffered by a subject resulting from participation in an experimental study

 Please specify if any insurance policy to protect participants will be opened-up;

* An insurance coverage is already in place
* An insurance policy will be opened-up for this study
* An insurance coverage is not needed

**FUNDING**

**25. Did your study receive a scientific evaluation at the date of the submission to the Ethics Committee?**

* Yes, please specify who reviewed the study:
* No

 **26.** **Is a funding for the study expected?**

* Yes
* No

**27. Did the study obtain a grant at the date of the submission to the Ethics Committee?**

* Yes
* No

**28. If the study is funded, please specify funder/program/call for proposal, project identification code/grant agreement number, amount of money received:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Funder**(i.e. MIUR, UE, company, etc.) | **Program**(i.e. CCM, Horizon2020, etc.) | **Call for proposal** | **Project identification code/grant agreement number** | **Amount** € |
|  |  |  |  |  |
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**USE OF BIOLOGICAL MATERIAL**

**29. Is the use of biological material planned?**

* Yes, new material will be collected
* Yes, material already collected and/or stored will be used
* No

**30. If a biological material collection is planned, please specify which material (multiple answers possible)**

* Tissue
* Blood
* Plasma
* Saliva
* Urine
* Other

**31. Is the biological material transfer between institutions/laboratories planned?**

* Yes
* No

**32. If yes, is a Material/Data Transfer Agreement planned?**

* Yes
* No

**33. Is the biological material storage planned?**

* Yes, in an in-house sample collection
* Yes, in an accredited biobank
* Yes, but at the end of the study the material will be destroyed
* No

**34.How long will be the material stored?**

* Material will be long-term stored (time not defined)
* Specify for how long the material will be stored

**35. Is genetic data processing\* expected?**

**\*** *According to the General Data Protection Regulation n. 2016/679 'genetic data' means: “personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question***”**

* Yes
* No

**STUDY RESULTS AND DATA PROPERTY**

**36. Is the study aimed at the industrial development of a product?**

* Yes
* No

**37. Please specify who is the owner of data related to the study and its results:**

* The centre/institution/organization that is submitting the study to the ISS EC
* Data will be shared
* Another (Other) centre/institution/organization (s) will be the only owner(s)

**38. Is a *Data Management Plan* drafted?**

* Yes
* No

**39. Will collected data be made available?**

* Yes
* No

**Date of compilation:**