

ENVIRONMENTAL MANAGEMENT PLAN EMP

Version 4.0, February 22, 2021

EMP procedures are in detail described in the IF Environment and Social Management Framework (ESMF). Environmental and Social Management Framework specifies environmental and social procedures for implemented projects to adhere to, including Environmental Management Plan, which are consistent with Serbian national legislation and safeguard policies.

Project IF ID: 50335

I. MITIGATION PLAN

No.	Phase	Issue	Mitigating Measure	Cost of Mitigation (If Substantial)	Responsibility*	Supervision observation and comments (to be filled out during supervision)
#1	Construction	Clinical trial needs to be registered in Medicines and Medical Agency of Serbia	Issuing a permit for registration from Medicines and Medical Agency of Serbia, for clinical trial of medical device class I, non-invasive with transient use.	22 000 RSD	Grant recipient	

<p>#2</p>	<p>Operation</p>	<p>Ethics principles need to be based on the Declaration of Helsinki on biomedical investigation on humans and with respect to ISO 14155 standard.</p>	<p>Statement that clinical trial will be conducted with the pursuant to ethic principles based on the Declaration of Helsinki will be signed and necessary steps will be followed:</p> <ul style="list-style-type: none"> • Usefulness and risks of the clinical trial will be evaluated • Inclusion and exclusion criteria for defining a group for clinical trial will be properly defined • Detailed protocol of clinical trial will be defined and 	<p>Insurance for subjects that participate in clinical trials: approx. 20 000 RSD per patient</p>	<p>Grant recipient</p>	
-----------	------------------	--	---	---	------------------------	--

			<p>followed</p> <ul style="list-style-type: none"> • Subjects in clinical trials will be insured • All subjects will be informed about the procedure, researchers that will provide the study and they will sign the informed consent that they are willing to participate in a clinical study (on Serbian language) 			
--	--	--	--	--	--	--

*Items indicated to be the responsibility of the contractor shall be specified in the bid documents

II. MONITORING PLAN

No.		What	Where	How	When	Monitoring Cost	Responsibility	Supervision
-----	--	------	-------	-----	------	-----------------	----------------	-------------

	Phase	parameter is to be monitored?	is the parameter to be monitored?	is the parameter to be monitored/ type of monitoring equipment?	is the parameter to be monitored- frequency of measurement or continuous?	What is the cost of equipment or contractor charges to perform monitoring?		observation and comments (to be filled out during supervision with reference to adequate measuring reports)
#1	Operation	Unwanted effects of a medical device	Clinical Center of Serbia	State of subjects will be monitored.	During the whole clinical trial grant recipient will be in charge to monitor any kind of unwanted effects.		Grant recipient	
#2	Operation	Clinical performance of a medical device	Clinical Center of Serbia	Primary and secondary outcomes defined with a protocol will be monitored.	Outcomes will be monitored based on the defined protocol. Frequency of measurements will be defined depending on the measured outcome.		Grant recipient	

III. PUBLIC CONSULTATION DETAILS AND MINUTES OF MEETING FOR THE ENVIRONMENTAL MANAGEMENT PLAN

In a separate document provide details on:

1. Manner in which notification of the consultation was announced: media(s) used, date(s), description or copy of the announcement
2. Date(s) consultation(s) was (were) held
3. Location(s) consultation(s) was (were) held
4. Who was specifically invited (Name, Organization or Occupation, Telephone/Fax/e-mail number/address (home and/or office)?)
5. List of Attendees (Name, organization or occupation, contact details)
6. Meeting Agenda
7. Summary Meeting Minutes (Comments, Questions and Response by Presenters)
8. List of decisions reached, and any actions agreed upon with schedules and deadlines and responsibilities.



INTERNAL USE:

Form reviewed and approved by: (Innovation Fund: Independent Environmental and Social Management Expert - IESME)	
Date	
Name	
Title	
Signature	