

**SERBIA ACCELERATING INNOVATION AND GROWTH  
ENTREPRENEURSHIP (SAIGE) PROJECT**

**Program PRISMA**

**ENVIRONMENTAL AND SOCIAL MANAGEMENT PLAN (ESMP)**

*Tailoring management of tick-borne diseases based on diversity of ticks and  
tick-borne pathogens (TalkToTick)*

**FINAL DOCUMENT**

Belgrade,  
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## ABBREVIATIONS AND ACRONYMS

PIU	Project Implementation Unit
ESMF	Environmental Social Management Framework
ESMP	Environmental Social Management Plan
WB	The World Bank Group
WMP	Waste Management Plan
IBA	Important bird area
IPA	Important plant area
IMI	Institute for Medical Research
MFUB	Faculty of Medicine, University of Belgrade
MFVMAUO	Faculty of Medicine, Military Medical Academy, University of Defense
SRO	Scientific Research Organization
PI	Principal Investigator
SAIGE	The Serbia Accelerating Innovation and Growth Entrepreneurship Project
SOP	Standard operating procedure
RS	Republic of Serbia
OSH	Occupational safety and health
WP	Work Package
UBFZF	Faculty of Philosophy, University of Belgrade
FBUB	Faculty of Biology, University of Belgrade
TBPs	Tick-borne pathogens
TBDs	Tick-borne diseases
LB	Lyme borreliosis
BMD	<i>Borrelia miyamotoi</i> disease
TBE	Tick-borne encephalitis
EU	European Union
GIS	Georeferenced
DNA	Deoxyribonucleic acid
RNA	Ribonucleic acid
COST	European Cooperation in Science and Technology
EtBr	Ethidium bromide
PPE	Personal protective equipment
DLP	Data Loss Protection

## EXECUTIVE SUMMARY

The environmental and social checklist screening carried out during the evaluation of the project is consistent with the ESMF classification and ranked the project as of moderate risk. The screening result shows that this project has low risk considering ethics and moderate considering the environment. The specific social risks relate to the protection of personal data. All raised concerns can be readily addressed through mitigation measures.

This ESMP is therefore prepared to set out specific mitigation, monitoring, and institutional measures to be taken during implementation to eliminate adverse environmental and social impacts, offset them or reduce them to acceptable levels.

All relevant Ethical approvals from participant institutions (IMI, MFUB, Clinical Centre of Republic of Serbia, MFVMAUO) are granted.

All necessary project specific stakeholder consent for sampling and permits will be provided during the implementation of the project upon the selection of sampling locations.

Leading SRO of the project, IMI, is the National institute of Republic of Serbia planned to be a part of the new BIO4 Campus in Belgrade – a strategic investment project to concentrate people, knowledge, and infrastructure to accelerate development in biodiversity, biomedicine, biotechnology, and bioinformatics. PI and members of the project team from IMI are part of Centre of excellence for food and vector-borne zoonoses, and PI of the project, Dr. Snežana Tomanović is a Head of Centre of excellence. IMI is also part of the SAIGE project that aims to enhance Serbia's growth and competitiveness by improving relevance and quality of scientific research. All these statuses imply already implemented or planned capacity building activities both in scientific and administrative section. During the project lifetime further activities will be foster to increase environment and social management capacities.

- Missing legal documents and project specific SOPs will be prepared and adopted
- Training manuals will be prepared and adopted
- Project team members will be internally trained for management of activities with potential environmental and social risk
- Project management activities will be outlined with requirements of WB
- Project office at leading SRO (IMI) will be formed

The purpose of the Environmental and Social Management Plan is to highlight the negative environmental impacts and management problems during the preparation and implementation of the research project "Tailoring management of tick-borne diseases based on diversity of ticks and tick-borne pathogens (TalkToTick)".

The key components of the Environmental and Social Management Plan are: the Plan for the mitigation of adverse impacts on the environment and the Plan for monitoring the impact on the environment.

## LEGAL AND ADMINISTRATIVE FRAMEWORK

### Relevant Institutions

The relevant Ministry of Environmental Protection of the Republic of Serbia is responsible for producing and implementing the environmental policy. Other relevant institutions are: the Institute for Nature Conservation of Serbia and the Institute for the Protection of Cultural Monuments.

### Existing Serbian legislation

All field work, sampling procedures, laboratory work, and waste management will be in concordance with the relevant laws and/or management strategies of the Republic of Serbia), including specific rulebooks:

- The Constitution of Serbia ("Official Gazette of RS" No. 98/06).
- The National Strategy for Sustainable Development ("Official Gazette of RS" No. 72/09, 81/09)
- Law on Science and Research ("Official Gazette of RS" No. 49/19)
- Law on environmental protection ("Official Gazette of RS" No. 135/04, 36/09, 72/09, 43/11, 14/16, 76/18 and 95/18)
- Law on Fire Protection ("Official Gazette of RS", Nos. 111/2009, 20/2015, 87/2018 and 87/2018)
- Law on waste management ("Official Gazette of RS", 36/09, 88/10, 14/16 and 95/2018) Law on noise protection ("Official Gazette of RS", 36/09, 88/10 and 96/2021),,
- Law on Health Care ("Official Gazette of RS", No. 25/2019)
- Law on protection of personal data ("Official Gazette of RS", No. 87/2018)
- Law on Occupational Health and Safety ("Official Gazette of RS", 101/05, 91/15 and 113/2017)
- Rulebook on preventive measures for safe and healthy work to prevent the occurrence and spread of infectious disease epidemics ("Official Gazette of RS", No. 94/2020),
- Rulebook on preventative measures for safe and healthy work when exposed to biological hazards ("Official Gazette of RS", 96/2010 and 115/2020)
- Rulebook on personal protective equipment ("Official Gazette of RS", No. 23/2020),
- Rulebook on preventive measures for safe and healthy work at the workplace ("Official Gazette of RS", Nos. 21/2009 and 1/2019),
- Rulebook on preventive measures for safe and healthy work when exposed to chemical substances ("Official Gazette of RS", Nos. 106/2009, 117/2017, 107/2021),
- Rulebook on the provision of signs for safety or health at work ("Official Gazette of RS", Nos. 95/2010 and 108/2017),
- Rulebook on the provision of first aid, the type of means and equipment that must be provided at the workplace, the method and deadlines for training employees to provide first aid ("Official Gazette of RS", No.109/2016),
- Rulebook on preventive measures for safe and healthy work when exposed to carcinogens or mutagens, ("Official Gazette of RS", Nos. 96/2011 and 117/2017),
- Rulebook on the provision of signs for safety and health at work ("Official Gazette of RS", Nos. 95/2010 and 108/2017)
- Rulebook on preventive measures for safe and healthy work when using work equipment ("Official Gazette of RS", Nos. 23/2009, 123/2012, 102/2015 and 101/2018),

- Rulebook on the procedure for inspecting and checking work equipment and testing working environment conditions ("Official Gazette of RS", Nos. 94/2006, 108/2006, 114/2014 and 102/2015),
- Rulebook on records in the field of safety and health at work ("Official Gazette of RS", Nos. 62/2007 and 102/2015),
- Rulebook on the manner and procedure of risk assessment at the workplace and in the working environment, ("Official Gazette of RS", Nos. 72/2006, 84/2006, 30/2010 and 102/2015).
- Rulebook on the manner of storage, packaging and marking of hazardous waste ("Official Gazette of RS", Nos. 92/2010 and 77/2021),
- Rulebook on categories, testing and classification of waste ("Official Gazette of RS", No. 56/10 and 93/2019),
- The Law on Packaging and Packaging Waste ("Official Gazette of RS", No. 36/2009 and 95/2018),
- Rulebook on the form of daily records and annual report on waste with instructions for its completion ("Official Gazette of RS", Nos. 95/10 and 88/2015),
- Rulebook on the form of the document on the movement of hazardous waste, the form of prior notification of the method of its delivery and instructions for filling it in ("Official Gazette of RS", Nos. 114/2013 and 17/2017),
- Rulebook on the document form on the movement of waste and instructions for its completion ("Official Gazette of RS", No. 72/2009),
- Rulebook on the method and procedure of pharmaceutical waste management ("Official Gazette of RS", No. 49/2019),
- Rulebook on medical waste management ("Official Gazette of RS", No. 48/2019),
- The Law on Copyrights and related Rights (Official gazette of RS 104/2009, 99/2011 from 27.12.2011 and 119/2012) This Law regulate the rights of the authors of literary, scientific and artistic works
- Rulebook on organizing fire protection according to the category of fire hazard ("Official Gazette of the RS", No. 6/2021),
- Law on Defence ("Official Gazette of RS", Nos. 116/07, 88/09, 104/09, 10/15 and 366/18),
- Law on Free Access to Information of Public Importance ("Official Gazette of RS", Nos. 120/2004, 54/2007, 104/2009 and 36/2010),

For the Institute of Medical Research (IMI), the relevant specific documents are:

Internal organization and systematization of workplaces (2021).

Act on risk assessment (2022).

Decision on appointing a fire protection manager (2022).

Fire protection rules (2023).

Training program for employees for occupational health and safety at work (2022).

Agreement on the Occupational health and safety management and monitoring (2023).

Decision on appointing responsible person for OSH (2022).

Rulebook-General Act on Occupational health and safety management (2022)

Decision on appointing a person responsible for waste management (2021).

Contract for medical waste disposal RAMONDIS (2019).

Waste management plan (2021).

Medical Waste management plan (2022).

For the BFUB, the relevant specific documents are:

Rulebook on usage of company cars (2014).

For the MFUB, the relevant specific documents are:

Contract for waste management (2023).

For the MFVMAUB, the relevant specific documents are:

Certificates for ISO 9001:2015, ISO 14001:2015, ISO 45001:2015

Manual for work in Department for Microbial genetics and Immunology VMA (2018).

Manual for prevention of Lyme disease VMA (2019).

Manual book for diagnostics and treatment of poisoning with chemical materials VMA.(2010).

Rulebook for safe waste management VMA (2011).

Rulebook for the evaluation of the environment VMA (2018).

Finally, relevant principles extracted from the laws, rulebooks, policy and guidelines will be incorporated into project specific standard operating procedures (SOPs) which will be created by the project team (described in WP1) and will cover:

- Field work
- Sample collection
- Personal data collection
- Laboratory work
- Laboratory safety and emergency procedures
- Public communication

## PROJECT DESCRIPTION

Project Proposal Title: Tailoring management of tick-borne diseases based on diversity of ticks and tick-borne pathogens

Acronym: **TalkToTick**

Sub-program: Biomedicine

Participating Scientific and Research Organization (SRO) and address:

Institute for Medical Research, National Institute of Republic of Serbia, University of Belgrade, Serbia (IMI), Dr. Subotića 4, Belgrade – 5 participants, PI, 3 WP leaders

Principal Investigator (PI) (Name and contact details): Dr. Snežana Tomanović, [snezanat@imi.bg.ac.rs](mailto:snezanat@imi.bg.ac.rs), phone +381631371459

Partner organizations on the project:

Faculty of Medicine, University of Belgrade (MFUB), Dr. Subotića 8, Belgrade – 2 participants, 1 WP leader

Faculty of Medicine, Military Medical Academy, University of Defense (MFVMAUO), Crnotravska 17, Belgrade – 1 participant

Faculty of Biology, University of Belgrade (FBUB), Studentski trg 16, Belgrade – 1 participant

Faculty of Philosophy, University of Belgrade (UBFZF), Čika Ljubina 18-20, Belgrade – 1 participant

### **Project Description**

The project addresses the globally observed discrepancy between the diversity of ticks and tick-borne pathogens (TBPs) and reported cases and clinical manifestations of tick-borne diseases (TBDs).

Overall awareness of tick's vector role is limited mainly to Lyme borreliosis (LB) or Tick-borne encephalitis (TBE), while many other TBDs are usually underdiagnosed or misdiagnosed. Even in the case of LB, the most notable TBD in Europe, it is supposed that many cases have been unrecognized, causing the "silent epidemic" affecting one million EU citizens.

The novelty of the project is in the stratified strategy of studying the diversity of TBPs transmitted from ticks to humans. The methodology involves two approaches - entomological (bottom-up) and clinical (top-down), that merge toward molecular identification and characterization of TBPs in humans. The entomological approach includes follow-up of patients with the bite of a tick positive to at least one TBP. The clinical approach includes patients with at least one clinical sign of TBD regardless of the record of a tick bite.

The expected results of the project are:

- determination of the etiological background of clinical cases and unclear states,
- establishment of a national database of TBPs and TBDs
- protocols supporting physicians in the decision on appropriate treatment



- raising awareness in the general population on TBPs affecting humans,
- permanent involvement of stakeholders in a timely and efficient manner to prevent transmission of TBDs.

TalkToTick project is structured in four work packages (WPs). Each work package will focus on a specific set of objectives, with tasks dedicated to each objective.

1. Entomological approach – TBPs in questing and ticks parasitizing humans
2. Clinical approach – TBPs in persons with tick bites and patients with clinical manifestations of TBDs
3. Integrating results from entomological and clinical approaches toward tailor-made management of TBDs.
4. Education and risen continuous interest of the professionals/stakeholders/public for the problem of TBDs and ticks in Serbia and sustainable preventive behavior

The project activities include field and laboratory work and work in the outpatient and inpatient clinic with patients.

Fieldwork is organized to collect tick samples from the vegetation and is carried out in land ecosystems. Five (5) localities frequently visited by humans and identified as high risk areas based on previous experience with humans with tick bites, will be selected as study areas.

Laboratory work will be carried out in dedicated laboratories of two partner institutions on the project – IMI and MFVMAUO. The laboratories used are entomological laboratory, molecular laboratory, laboratory for in vitro work with microorganisms, and general laboratory in IMI, and laboratory for microbiology and immunology at MFVMAUO.

Clinical examination of the patients will be conducted in outpatient and inpatient facilities in the Clinic for Tropical and Infectious Diseases, and Clinic for Dermatovenerology of the Clinical Centre of Serbia, MFUB. The study design doesn't require any additional usage of facilities or consumables apart from regular clinical examination and monitoring of patients with tick bites and TBDs who are treated at these clinics. Regular medical treatment of patients is covered by Republic Health Insurance Fund.

During the project implementation, the following data will be generated or used:

- georeferenced (GIS) sample data
- environmental data on ticks' collection sites
- species data
- genomic data
- personal data of patients
- clinical data of patients
- new protocols and methods

By type, gathered data are observational, experimental, and derived.

Environmental data on ticks' collection sites include secondary data (daily, monthly, or annual information on weather parameters of the study region) from the open databases (Republic Hydrometeorological Service of Serbia, Copernicus) and primary data – weather data collected using transportable meteorological measuring stations during sample collection (ground temperature and humidity), data on vegetation cover and land use.

The patients' personal data will be collected through questionnaires filled by participants with tick bites and patients with clinical symptoms of TBDs. Data will include name, year of birth, gender,

contact information, date and location where the tick bite occurred, a body part of the tick bite, information on previous tick bites, antibiotic therapy, chronic diseases, pregnancy. These data will be collected and stored upon the written consent for participation in the research and according to the legislation Law on Personal Data Protection (“Official Gazette RS”, no. 87/2018) and other Laws of reference to the research field. The size of personal data depends on the current epidemiological situation, and by the proposal is limited to data regarding the maximum of n=500 persons with a tick bite. The data size of isolated borrelia strains depends on eco-epidemiological situation and success of isolation and is limited to maximally expect 50.

The patients' clinical data include information on symptoms, medical condition, laboratory (biochemical, microbiological, and immunological) parameters, response to treatment, and outcome of the disease. Further, these data include biobank of DNA/RNA isolated from human samples. Biobank will be stored in a deep freeze storage facility (IMI, MFUB, MFVMAUO).

All data will be stored in digital form on a dedicated server (IMI) and primary data collected during field sampling will be additionally stored in paper form in laboratory protocols (IMI).

Data will be shared with authorized team members responsible for clinical monitoring (MFUB, MFVMAUO) using Microsoft office package and safe email communication.

This project's vital aspect is an increased scientific background and involvement of stakeholders and the general public in preventing TBDs. For its national and international importance project is facilitated by letters of support from COST action CA21270 PRAGMATICK, chaired by Institute of Evolution, Centre of Ecological Research, Budapest and Letter of support from President, Republic commission for the protection of the population from communicable diseases, Belgrade.

## ASSESSMENT OF THE POTENTIAL ENVIRONMENTAL AND SOCIAL IMPACTS OF SPECIFIC TASKS WITHIN THE PROJECT

### ***Potential impact on sampling sites***

The realization of this project will not directly impact air, water or soil quality in any way. Fieldwork will require the use of a field vehicle (FBUB), for total of 48 working days (twice a month during first 24 months of the project implementation). Field activities will be realized in the urban and peri-urban areas where vehicles are common, the additional emissions by one car are considered negligible. Sampling is performed by two researchers, manually, without any mechanical devices or machines, using a white flannel blanket (contact surface 1 m<sup>2</sup>), over the leaf litter and low vegetation. The procedure doesn't produce any noise, heat, waste or emissions. Sampling is designed to exclude any accidental trapping of other insects or invertebrates, only active ticks are collected, so impact on diversity on collecting sites is negligible. There won't be any disruption of local ecosystem during collection of the ticks, according to Law on Environmental protection.

### ***Potential biohazard impact on the environment and citizens***

Collected ticks are safely packed on the sampling site and transferred to the lab (IMI) in the plastic tubes tightly sealed with caps, packed in the zip bags with sticky mats to prevent accidental escape of potentially infected ticks and transmission to another location.

Two pathogens isolated and cultivated during the implementation of the project are *Borrelia burgdorferi* sensu lato, the causative agent of LB and *Borrelia miyamotoi*, the causative agent of B.

miyamotoi disease (BMD). These pathogens are transmitted solely by tick bite, so there is no risk of biohazard in the case of accident (spilling the culture in liquid medium) during the laboratory work.

### ***Potential impact of generated waste***

During the implementation of the project following types of waste will be generated – solid non-biological waste, solid potentially infectious waste, liquid hazardous waste, liquid potentially infective and infective waste.

Solid non-biological waste (plastic consumables, packaging and paper) will be disposed of according to the waste management plans at each SRO. Potentially infectious solid waste (plastic tips, tubes, columns) will be physically inactivated (autoclaving/freezing) prior to discarding in labeled biohazard bags in accordance with the waste management plans and contracts with medical waste removal companies at each SRO. Liquid potentially infective or infective waste (spent growth media, buffers, saline) will be collected in plastic flasks/bottles and chemically inactivated for at least 24h using sodium hypochlorite at a final concentration of 10%, after which the solution can be safely discarded in the laboratory drains. Liquid waste with potentially hazardous chemicals will be stored in glass bottles until pickup and disposal by the waste management company. Medical waste and consumables used for manipulation of medical waste will be collected in special biohazard cans, inactivated for at least 24h using sodium hypochlorite at a final concentration of 10% and disposal according to SROs plan for medical waste and pickup by the medical waste managed company contracted by SROs operating with such material (IMI, MFUB, MFVMAUO).

Solutions containing ethidium bromide (EtBr) (electrophoresis buffer) will be filtered using activated charcoal filters to remove EtBr prior to discarding in the laboratory drain. Agarose gels will be exposed to UV light for several days prior to discarding in hazardous waste bags and pickup by the waste management company.

### ***Potential impact on the health and safety of the project team***

The safety of the project team is paramount. All team members are public employees of certified SROs obligated to follow national Law on Occupational Health and Safety and other legal documents concordant with occupational safety. Training of the project team in the methodology will be administered by the most experienced team members prior to the start of the project activities covered by the SOPs, while regular refresher training will be administered during the project lifetime at a 1-year interval. The initial training is expected to include hands-on work at field and the laboratory bench within the SRO which will be responsible for each task described in the work packages, while refresher training will occur at meetings and consist of short visual presentations on each topic followed by discussion. General work in the laboratory will be under the umbrella of IMI specific documents - Training program for employees for occupational health and safety at work (2022), Agreement on the Occupational health and safety management and monitoring (2023), and Rulebook-General Act on Occupational health and safety management (2022). Prior to the start of related project activities, Rulebook on laboratory work will be developed and adopted.

Work in the laboratory with infectious and potentially infectious material - will be handled in accordance with Law on Occupational Health and Safety ("Official Gazette of RS", 101/05, 91/15 and 113/2017), Rulebook on preventative measures for safe and healthy work when exposed to biological hazards ("Official Gazette of RS", 96/2010 and 115/2020), Rulebook on preventive measures for safe and healthy work at the workplace ("Official Gazette of RS", Nos. 21/20109 and 1/2019), Rulebook on preventive measures for safe and healthy work when using work equipment ("Official Gazette of RS", Nos. 23/2009, 123/2012, 102/2015 and 101/2018).

Working with the laboratory burner - will be handled in accordance with the Law on Fire Protection ("Official Gazette of RS", Nos. 111/2009, 20/2015, 87/2018 and 87/2018) and the Rulebook on organizing fire protection according to the category of fire hazard ("Official Gazette of the RS", No. 6/2021).

### ***Project team PPE requirements***

During the realization of this project, several activities may impact the safety of the project team: field work, working with potentially infectious materials and/or hazardous waste. For field work and sample collection dedicated team members will be outfitted with special personal protective equipment which will consist of: field shoes, latex gloves, protective safety work wear, repellent application, portable first aid kits. All field work will be covered by official SRO policy/guideline documents (guideline on the use of 'company cars' of FBUB) and leave permits as well as SOPs. Laboratory work protective clothe and equipment consist of: lab coats, latex gloves, eye protection (goggles).

### ***Potential impact of personal data security***

The project activities include collection of personal data of participants enrolled in the study. Data will be collected through questionnaires filled by participants with tick bites (entomological approach) and patients with clinical symptoms of TBDs (clinical approach). Data will include name, contact information (set A), year of birth, gender, date and location where the tick bite occurred, a body part of the tick bite, information on previous tick bites (set B), antibiotic therapy, chronicle diseases, pregnancy (set C). Data set A will be used exclusively for contact with the patients during the study, data set C and year of birth will be used for identification of the exclusion criteria of the participants in the study, and data set B will be used as research data for analysis in the study. These data will be collected and stored upon the written consent for participation in the research and according to the legislation (Law on Personal Data Protection) and Ethical approval of IMI. The size of personal data depends on the current epidemiological situation, and by the proposal and Ethical approval is limited to data regarding the maximum of n=500 persons with a tick bite. During the data collection, only authorized team members from IMI are present. Data are written in paper questionnaires which are safely stored in locked laboratory protocols folders after converting into digital form, which will be stored at a safe IMI server, with limited access restricted only to project participants Data needed for further medical monitoring of participants (data sets A and B) by the team members from MFUB are transferred to them in digital form via safe email communication.

Within the clinical approach, name, contact information (set A), date of birth, information on previous tick bites, and medical parameters/data (set B), antibiotic therapy, chronicle diseases, pregnancy (set C) will be collected upon the written consent of participants at MFUB, according to the Ethical approval of MFUB and the University Clinical Center of Serbia. Data set A will be used exclusively for contact with the patients during the study, data set C and year of birth will be used for identification of the exclusion criteria of the participants in the study, and data set B will be used as research data for analysis in the study. During the data collection, only authorized team members-clinicians from MFUB are present. Data are written in paper questionnaires safely stored in locked clinical protocols folders. All data are transferred into digital form in the Access database of similar stored at a safe MFUB server. Data needed for further analysis of results (data set B) by team members from IMI and MFVMAUO are transferred to them in digital form via safe email communication. During the data collection, only an authorized team member from MFVMAUO is present. Data are written in paper questionnaires safely stored in locked protocol folders.

All data collected for research purposes will be analyzed without the possibility of determining the identity of the patients. All patients' answers collected in the paper form of the questionnaire will be transferred from paper format to electronic format. The electronic database will be stored on the principal researcher's computer, which is protected by a username and password. The data collected through the research will be published in a summary form, as part of the scientific research work. The above data will be stored on the principal researcher's computer and in paper form for a period of five years after the publication of the scientific publication.

Data storage and data access will be managed in accordance with Rulebook on the security of information and communication systems at Institute for Medical Research, National Institute of Republic of Serbia, University of Belgrade (2021). The data will be stored in electronic form on the IMI's server, which is protected by a password and an antivirus program. Access to the data will only be granted to authorized persons who are in charge of data processing and analysis, and who have signed a statement on data confidentiality. The data will also be stored in printed form in locked cabinets in the premises of the Institute, to which only authorized persons will have access.

### ***Safe storage and use of data, including data security***

The measures that will be taken to ensure the secure storage and use of data include the following:

- Regular updating of the antivirus program and operating system on the server and computers used for data processing.
- Using strong passwords to access the server and computers, which are changed every six months.
- Backing up data on external devices that are also stored in a secure location.
- Using encrypted emails to send and receive data between collaborators and project partners.
- Destruction or return of data after completion of the project, in accordance with legal regulations and ethical principles.

Protection of communication via email

Two-factor authentication, email encryption and Data Loss Protection (DLP).

### ***Potential socio-economic impact***

The project doesn't have any negative socio-economic impact; contrary, the significant potential impact is projected and expected. The information and guidelines TalkToTick will provide enables adequate prevention, diagnostic, and treatment methods, lowering the cost of health care, productivity loss, and absence from work. The results and recommendations produced during the implementation of the project are the systematic informational base for stakeholders to generate adequate public health policy and legislation instruments and tools for managing TBDs, leading to the project results' long-lasting impact. Based on the results and recommendations, healthcare professionals can adopt and apply the best medical practice, reduce the risk of misdiagnosis and treatment time, and decrease the use of antibiotics. Citizens exposed to tick bites either professionally or during recreational activities are educated for the most appropriate prevention measures and finally, reliable information would lower the level of stress-related to exposure to ticks, providing sense of psychological control and agency over potentially risk situations. The broader scientific community, as well as other beneficiaries such as companies that produce diagnostic tests or antimicrobial agents, will indirectly be impacted by the results of this project, i.e., with new information useful for the establishment of novel research or development of new products.

## SUMMARY OF ENVIRONMENTAL AND SOCIAL IMPACT

During the preparation and implementation phase, of the scientific research project *Tailoring management of tick-borne diseases based on diversity of ticks and tick-borne pathogens (TalkToTick)* there are certain/potential environmental impacts listed below, together with the intensity of their actions.

**Table 1** - Review of the impact on the environment that are predicted for the duration of the project

INFLUENCE	SIGNIFICANCE	COMMENT
Impacts on land use and settlements	Does not exist	During the realization of the project, there will be no expropriation of land
Ground and surface water	Low	Due to the low amount of water that can come to the recipient by drainage, the consequential impact is minimal to negligible
Air quality	Low	Temporary impact
Flora and fauna (protected areas and species)	Low	Under the terms of the Institute for Nature Conservation of Serbia
Noise	Low	Temporary impact
Soil management	Low	With the application of appropriate measures of waste management
Management of Waste	Low	Ensured through environmental management – waste and wastewater management plan will be prepared and implemented
Working in the field	Moderate	In accordance with existing protocols and application of measures for safe working in the field. During the fieldwork, members of the project team could be exposed to the bites of potentially infected ticks, or other pathogens or animals present in the environment. With the application of appropriate protective equipment and training of personal the impact is decreased.
Management of hazardous materials, including hazardous waste	Low	Ensured through management of hazardous materials, including hazardous waste, SRO has adopted the Waste management plan (2022) that will be implemented during the project activities
Medical waste management	Low	Ensured through management of medical waste, SROs have adopted the plan for medical waste and pickup by the medical waste managed company contracted by SROs operating with such material.
Working in the laboratory including Life and Fire Safety	Moderate	In accordance with existing procedures on H&S. During the work in the laboratory, members of the project team could be exposed to dangerous chemicals or infectious agents. With the application of appropriate protective equipment,

**Table 1** - Review of the impact on the environment that are predicted for the duration of the project

INFLUENCE	SIGNIFICANCE	COMMENT
		and personal training, the impact is decreased. Also, adequate control measures are aligned with safety procedures related to working with chemicals or infectious agents.
Safe management of chemicals, biohazards and hazardous materials	Low	Ensured through management of chemicals, biohazards and hazardous materials – management plan will be prepared and implemented
Handling of gases under pressure (H&Sat work and prevention of accidents)	Does not exist	During the realization of the project, there will be no handling of gases under pressure.
Health&Safety of the local populations (Field activities)	Low	Ensured through the applied environmentally safe sampling procedures that produce no noise, heat, waste or emissions
Cumulative impacts	Moderate/minor	Temporary, field and laboratory work could produce chemical and potentially infectious/infectious waste during the work, and members of the project team could be exposed to potentially accidental situations during field and laboratory work.

## ***MITIGATION PLAN***

<b>Phase</b>	<b>Issue</b>	<b>Mitigating Measure</b>	<b>Cost of Mitigation (If Substantial)</b>	<b>Responsibility</b>	<b>Supervision</b>
Project preparation	Review of existing contracts with waste management companies for possible quantity limits	Creation of annexes if required	None anticipated for annexing; possible costs due to quantity will be covered by SROs or project overhead.	PI; SROs. PI; SROs legal offices.	PIU/SF/IMI
Project preparation	Lack of project specific SOPs prepared for field work; sample collection and processing; isolation and in vitro culture; molecular detection and identification; and laboratory safety and emergency procedures	Creation of appropriate documents	None	PI and WP leaders.	PIU/SF/IMI
Project preparation	Lack of project specific stakeholder consent for sampling, permit requests, and forms for expression of interest statements for contributing to white paper.	Creation of appropriate forms.	None	PI and WP leaders.	PIU/SF/IMI
Project preparation	Existing laboratory competence training needs advancement and upgrade to expert project specific levels.	Expert project specific hands-on training and manuals provided, and proficiency testing administered to team members prior to execution of WPs.	None	PI and WP leaders.	PIU/SF/IMI
Project implementation	Emissions by vehicle used for field work.	One car will be used to visit multiple sites.	None	PI and WP1* leader	PIU/SF/IMI



Project implementation	Life and fire safety (LFS) procedures in fieldwork	All researchers are familiar with the current Evacuation Plan and Protection and Rescue Plan. All researchers are familiar with the dangers of fire and fire protection measures and are trained in handling fire extinguishers, hydrants and other devices used for extinguishing fires by the Law. All researchers in the Project are familiar with the "Instructions for action in case of fire".	None	PI and responsible person for the fire	PIU/SF/IMI
Project implementation	The existence of several sites under various levels of governmental protection in the sampling area.	Sampling will occur only on sites with public access and/or sites covered by owner or administrator permit.	None	PI and WP1 leader	PIU/SF/IMI
Project implementation	Exposure of team members to potentially accidental situations during the fieldwork (bites of potentially infected ticks, or other pathogens or animals present in the environment)	Sampling performed by experienced and previously trained team members, SOPs for field work prepared and adopted and protective equipment provided.	None	PI and WP1 leader	PIU/SF/IMI
Project implementation	Existence of infectious waste	Disposal according to medical waste management plan contracted registered services for medical waste removal; inactivation protocols adopted and implemented for all infectious waste.	None	PI and WP1 and WP2* leaders.	PIU/SF/IMI
Project implementation	Existence of project specific chemical waste	Disposal according to waste management plan, contracted	None	PI and WP1, WP2 and WP3* leaders.	PIU/SF/IMI

		registered services for chemical waste removal, along with adoption and implementation of additional filtration and neutralization/deactivation protocols.			
Project implementation	Handling of potentially hazardous chemical or biological materials.	SOPs for laboratory procedures prepared and adopted, specific training and PPE provided, obligatory PPE use; adherence to all SOPs.	None	PI and WP1, WP2 and WP3 leaders.	PIU/SF/IMI
Project implementation	Handling sensitive personal data collected during the project implementation	Ethical approval was provided, SOPs for personal data management and storage were prepared and adopted, authorization of team members for data management and coding of samples.	None	PI and WP1 and WP2 leaders	PIU/SF/IMI
Project implementation	Negative participant emotions (fear) concerning the findings in attached ticks of in clinical samples	Three medical doctors, two experienced senior clinicians and professors of the Medical faculty, and one subcontracted physician-specialist for infectious diseases with over 10 years of experience in outpatient clinics are engaged to be in dedicated contact patients presenting the results of the analysis	None	PI and WP2 leader.	PIU/SF/IMI
Project implementation	Insufficient interest of participants to be included in the study	Communication plan prepared and adopted, extensive communication activities	None	PI and WP4* leader	PIU/SF/IMI

		performed via electronic media, social networks, primary medical practice			
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WP1\* - Entomological approach – Tick-borne pathogens in questing and parasitizing ticks

WP2\* - Clinical approach – Tick-borne pathogens in persons with tick bites and patients with clinical manifestations of tick-borne diseases

WP3\*- Integrating results from entomological and clinical approach toward tailor made management of tick-borne diseases

WP4\* - Dissemination and communication

## ***MONITORING PLAN***

<b><i>Phase</i></b>	<b><i>What parameter is to be monitored?</i></b>	<b><i>Where is the parameter to be monitored?</i></b>	<b><i>How is the parameter to be monitored/ type of monitoring equipment?</i></b>	<b><i>When is the parameter to be monitored frequency of measurement or continuous?</i></b>	<b><i>Monitoring Cost</i></b>	<b><i>Responsibility</i></b>	<b><i>Supervision</i></b>
Project preparation	Contracted waste quantity (in case of annexing only).	SRO laboratories (IMI, MFUB, MFVMAUO)	On-site visual assessment and checks of dated and signed documentation.	Once, prior to commencing work	None	Designated person at SRO should conduct monitoring and notify the PI.	PIU/SF/IMI
Project preparation	Created SOP documents	SRO laboratories (IMI, MFVMAUO), dedicated	Laboratory/on-site visual assessment and checks of dated and	Once, prior to commencing work	None	PI	PIU/SF/IMI

	and training manuals.	internal project cloud	signed documentation.				
Project preparation	Stakeholder signed consent forms and sampling permits.	Leading SRO (IMI) laboratory/office (project documentation/archives).	Laboratory/on-site visual assessment and checks of dated and signed documentation.	Once a year	None	PI, WP1 leader	PIU/SF/IMI
Project preparation	Team members involved in field and lab work finished training activities	Leading SRO (IMI) laboratory/office (project documentation/archives).	Laboratory/on-site visual assessment and checks of dated and signed documentation.	Once a year	None	PI	PIU/SF/IMI
Project implementation	Working environment monitoring	Leading SRO (IMI) administrative unit	Visual assessment of report of Agreement on the Occupational health and safety management and monitoring	Once a year	None	PI	PIU/SF/IMI
Project implementation	Field work protective equipment available and functional	FBUB field vehicle	On-site visual assessment and checks of equipment	Prior to every field trip	None	WP1 leader performs check and informs PI	PIU/SF/IMI

Project implementation	Infectious waste inactivation and disposal operational and sodium hypochlorite at a final concentration of 10% provided and used	SRO laboratories (IMI, MFUB, MFVMAUO)	On-site visual assessment and checks of equipment	continuous	None	Team members working in the laboratory performs check and informs PI	PIU/SF/IMI
Project implementation	Personal data protection system established and operational	SRO laboratories (IMI, MFUB)	On-site visual assessment and checks of paper and electronic protocol folders	Once a year	None	WP1 and WP2 leaders perform a check and inform the PI	PIU/SF/IMI
Project implementation	Increased level of knowledge and positive attitude toward personal protective measures against tick bites and	Leading SRO (IMI)	Follow up questioners for workshop participants	Two times during the project implementation, after workshops organized	None	PI	PIU/SF/IMI

	tick-borne diseases						
Project implementation	Life and fire safety (LFS) procedures in the laboratory	Laboratory of the institution implementing the project.	Visual inspections and checks of the documentation	Periodically during the implementation of the project	None	PI	PIU/SF/IMI



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

The call for public consultation for the ESMP document for the *TalkToTick* project has been published in the news section of the website of the Institute for Medical Research, National Institute of the Republic of Serbia, University of Belgrade (IMI), the leading SRO of the project. The call was published on Monday, December 4, 2023 and contained all relevant information about the purpose of the call, the date of the planned consultations (December 12, 2023, 13:00), the location, the email address where interested parties can register to participate in the public consultations and send proposals and questions, as well as the deadlines for proposals and questions (December 11, 2023, 16:00 local time) and registration for the public consultations (December 12, 2023, 11:00). The link to the ESMP document was also published in the call.



The screenshot shows the website of the Institute for Medical Research, National Institute of the Republic of Serbia, University of Belgrade (IMI). The header includes the IMI logo and navigation links for 'NOVOSTI', 'SARADNA', 'KARIJERA', and social media icons. The main content area features the title 'Јавне консултације за пројекат Tailoring management of tick-borne diseases based on diversity of ticks and tick-borne pathogens (TalkToTick)' in red. Below the title, it states the announcement date as 04-12-2023. The text explains that according to the World Bank's 'Opportunity Bank' for managing the project's impact on the environment and society, the IMI is calling for public consultations. It lists the interested parties as the public, organs, and organizations. A link to the project website (<https://www.imi.bg.ac.rs/>) is provided. The text also mentions that interested parties can view the project documents on the IMI website. It specifies that proposals and questions should be submitted to the IMI office in written or electronic form by December 11, 2023, at 16:00. The public consultations and presentation of the project documents will be held on December 12, 2023, at 13:00 in the library of the IMI. The location is the Bulvar oslobođenja broj 18. It also states that registration for the consultations should be sent to the IMI office by December 12, 2023, at 10:00 via electronic mail to [office@imi.bg.ac.rs](mailto:office@imi.bg.ac.rs). Finally, it provides a link to the ESMP document for download.

The

Consultation took place on Tuesday, December 12, 2023, starting at 13:00

The consultation took place in the library of the Institute for Medical Research, National Institute of the Republic of Serbia, University of Belgrade (IMI), the leading SRO of the project.



The following persons were specifically invited:

University professor in the field of microbiology, Faculty of Pharmacy University of Belgrade

PhD student in Parasitology, Faculty of Veterinary Medicine University of Belgrade

PhD student in Ecology, Faculty of Biology University of Belgrade

General public representative, economist, enterprenurer, Belgrade

The following persons attended the consultation:

University professor in the field of microbiology, Faculty of Pharmacy University of Belgrade

PhD student in Ecology, Faculty of Biology University of Belgrade

General public representative, economist, enterprenurer, Belgrade

Following *TalkToTick* team members were present on the consultation.

PI, TM1, TM2, TM3, TM4, TM8



**Photo 1.** Public discussion in the library of the Institute for Medical Research, National Institute of the Republic of Serbia, December 12, 2023.

## Meeting Agenda:

- Presentation of the *TalkToTick* project – PI
- Presentation of the ESMP document – PI
- Discussion
- Conclusions

## **Summary Meeting Minutes** (Comments, Questions and Response by Presenters)

The meeting began at 1.10 pm. The PI welcomed the participants, introduced the team members present and introduced the audience to the institution and the aim of the public consultation. PI briefly introduced the project, highlighting the main objectives, results, and impact of the project on stakeholders, and then presented the concept and methodology of the project. PI then presented the ESMP document, highlighting the main risk points of the project and the means to mitigate and monitor the measures.

PI opened the discussion and invited those present to ask questions and make suggestions.

University professor in the field of microbiology generally stated that the project is well planned, and the expected results will have a significant impact on the development of the most appropriate diagnostic and therapeutic protocols for tick-borne diseases. She inquired about the protocol for the isolation and cultivation of *Borrelia* spirochetes and the safety measures for microbiological work in the laboratory that will be implemented as part of the project.

PI invited TM1 to address these questions, as she is the most experienced team member in the isolation and cultivation of *Borrelia*. TM1 explained that IMI has adequate laboratory resources with BSL2 cabinet and established protocols for the isolation and cultivation of *Borrelia*, that all necessary protective measures are taken for team members involved in these activities, and that all waste generated during isolation and cultivation is disposed of according to IMI's waste management plans. TM1 added that the pathogens to be isolated and cultured are transmitted by ticks and cannot be transmitted by accidental spillage in the laboratory.

General public representative said he spends a lot of time in recreational areas where he is exposed to tick bites, and is particularly interested in including people with tick bites in the project study. General public representative said he was aware that a commercial service for tick analysis for *Borrelia* has been available at the IMR for more than 10 years and asked the team members about the details of the analysis of ticks on people with tick bites.

PI explained that for those individuals with tick bites who are willing to participate in the study, an advanced tick analysis for a range of tick-borne pathogens, not just *Borrelia*, will be provided free of charge, followed by monitoring of health status for possible tick-borne analysis by experienced clinicians – infectious disease and dermatology specialists. This approach will ensure

the maximum health safety of participants and prevent excessive and unnecessary use of antibiotics, which could lead to the emerging problem of massive antibiotic resistance. PI added that all personal data collected from the study participants will be processed strictly according to the data management plan, will be anonymized in all possible ways and will be accessible only to authorized team members.

PhD student in Ecology said that she was particularly interested in the collection of tick samples from vegetation and asked how the maximum efficiency of sampling will be ensured with regard to weather conditions.

PI invited TM3 to address this question, as he is the head of WP1, which includes field sampling. TM3 explained that sampling is conducted every month for 2 consecutive years using a standardized sampling method at 5 sites selected based on previous ecological and epidemiological data. Two team members will be involved in each sampling. In this way, the data obtained will be reliable.

The meeting ended at 2PM

## **Conclusion**

List of decisions reached, and any actions agreed upon with schedules and deadlines and responsibilities.

- All participants agreed that the *TalkToTick* project is of great interest to public health, the scientific community and the general public.
- Based on the discussion, it was decided that the project should serve as a focal point for additional activities to be defined.

Public consultation report reviewed by Environmental and Social Expert:

Date: 15.12.2023.

Title: ESE/PIU SAIGE