

DIGITAL, INNOVATION, AND GREEN TECHNOLOGY PROJECT (DIGIT PROJECT)



REPUBLIKA HRVATSKA
Ministry of Science,
Education and Youth



THE WORLD BANK
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REPUBLIC OF CROATIA
MINISTRY OF SCIENCE, EDUCATION AND YOUTH
Donje Svetice 38, Zagreb 10 000, Croatia

DIGITAL, INNOVATION, AND GREEN TECHNOLOGY PROJECT (DIGIT PROJECT)

IBRD LOAN NO. 9558-HR

PROJECT ID: P180755



ESMP CHECKLIST

CALL FOR PROPOSALS “SEAL OF EXCELLENCE UNDER THE SYNERGIES PROGRAM”

CALL REFERENCE NUMBER: DIGIT.2.2.01

June 2025

ESMP CHECKLIST

The template presented below will be revised for specific projects to reflect scope of works and E&S concerns.

The ESMP Checklist provides “pragmatic good practice” and it is designed to be user friendly and compatible with WB safeguard requirements. The checklist-type format attempts to cover typical mitigation approaches to common civil works contracts with localized impacts.

This document will help assess potential environmental impacts associated with the proposed project, identify potential environmental improvement opportunities and recommend measures for the prevention, minimization and mitigation of adverse environmental and social impacts.

ESMP Checklist is a document prepared and owned by final beneficiary. The Beneficiary is responsible for the implementation of the ESMP Checklist as well as any subsequent corrective measures prescribed by PIU and WB.

The checklist has one (1) introduction section and three (3) main parts:

Introduction or foreword part consisted of following sections:

- *Introduction* (project description),
- *Environmental and social category* (environmental and social category is defined),
- *Potential environmental and social impacts* (potential impacts are defined)
- *ESMP Checklist* (concept and application of Checklist are explained),
- *Monitoring and reporting* (brief description of the monitoring and reporting process including responsibilities of involved stakeholders)

Part 1 - constitutes a descriptive part (“site-passport”) that describes the project specifics in terms of physical location, the institutional and legislative aspects, the project description, inclusive of the need for a capacity building program and description of the public consultation process.

Part 2 - includes the environmental and social screening in a simple Yes/No format followed by mitigation measures for any given activity.

Part 3 - is a monitoring plan for activities during project construction and implementation. It retains the same format required for standard World Bank ESMPs.

ESMP Checklist implementation report will be submitted to WB semi-annually if not agreed differently.

Workers code of conduct (subject to WB approval) will be a part of bidding documentation and contracts with Contractors. Code of conduct will extend to sub-contractors and be a part of Contractor’s contractual agreements.

Part I - General project and site information

INSTITUTIONAL & ADMINISTRATIVE				
Country	Croatia			
Project title	IgG glycome composition as a biomarker for personalised prevention and management of cardiovascular diseases GlycoCardio 2023			
Scope of project and activity	<p>The GlycoCardio PoC project is an attempt of Genos, the global leader in high throughput glycomics, to prove the concept of IgG glycans as a personalised navigator for management of cardiovascular disease risk. Despite advancements in treatment and prediction, cardiovascular diseases (CVD) are still the number one killer that is accountable for 33% of global deaths. One of the key problems in the management of CVD risk is the fact that each of us is different and most interventions are not optimal for any given individual. However, biomarkers for personalized preventive medicine are lacking.</p> <p>Contrary to genetic risk factors that are given for life, glycan risk factors are dynamic and can be modified by both lifestyle and pharmacological interventions. Furthermore, there is significant evidence that IgG glycans are not only biomarkers, but also active participants in the development of CVD through their role in the regulation of low-grade chronic inflammation. However, the dynamics of changes in IgG glycans is very slow and it is not known whether current analytical precision is sufficient to monitor changes at the level of an individual within a realistic time frame needed to evaluate lifestyle interventions. Though GlycoCardio PoC project we will perform a validation study in "real-world" setting to see whether this concept is viable. If so, then even minor effects in reducing the risk of CVD will have major impact on both society and economy at the global level.</p>			
Institutional arrangements (WB) (Name and contacts)	(Task Team Leader)		Environmental/Safeguards Specialists:	
Implementation arrangements (Borrower) (Name and contacts)	Safeguard/Environment Supervision Helena Deriš hderis@genos.hr	Works supervisor Ivan Gudelj igudelj@genos.hr	Inspectorate Supervision Ana Savanović Ana.savanovic@adria-grupa.hr	Works Contactor Filip Šoštarić fsostaric@genos.hr
RESEARCH DESCRIPTION				
Objectives and Scope of the Research	<p>Objectives: The main goal of the GlycoCardio project is to prove the concept that IgG glycans can be used as a personalized biomarker for managing cardiovascular disease (CVD) risk. The project aims to develop a tool for personalized prevention and management of CVD that provides objective feedback on the effectiveness of lifestyle and pharmacological interventions. A key objective is to develop a test that can reliably quantify changes in an individual's CVD risk within a few months of an intervention, which is expected to motivate people to adopt healthier habits.</p> <p>Scope: The research will focus on validating specific IgG glycans as indicators of future CVD events. The project includes analyzing samples from a large prospective cohort to confirm sex-specific differences in these biomarkers. It will also involve a "real-world" validation study to see if lifestyle and pharmacological interventions affect the GlycoCardio risk score. Finally, the project will develop a dedicated mobile app to calculate and present the dynamic risk score to end-users. The initial scope for the test will be for women, with plans to extend it to men after further research.</p>			

Research Methodology and Materials Used	<p>The project will use a three-task approach:</p> <p>Additional Research: Analyze IgG glycome composition in 600 incident heart attack and stroke cases from the German Chronic Kidney Disease (GCKD) cohort to validate and define sex-specific risk scores.</p> <p>"Real World" Validation: Analyze data from at least three cohorts undergoing exercise, nutritional, or pharmacological interventions (conducted by partner company GlycanAge) to see how these interventions affect the GlycoCardio risk score.</p> <p>App Development: Develop a calculator and app that uses raw glycan data from the GlycanAge test to determine the GlycoCardio risk score.</p> <p>Materials Used: The research will utilize samples from the GCKD study. It will also use samples from individuals participating in lifestyle intervention studies organized by the partner company, GlycanAge Ltd. Samples will be analyzed according to the standard glycome analysis used in Genos (already used for analysis of more than 200 000 samples). The project requires consumables and reagents for IgG glycome analyses, including enzymes, labeling reagents, and laboratory plastics.</p> <p>The study may potentially include individuals from vulnerable groups, including women of reproductive age. All necessary precautions will be taken to ensure their safety and to protect their rights, in full compliance with relevant ethical guidelines and regulatory requirements. Participants will be thoroughly informed about the study, and specific safeguards will be implemented where appropriate.</p> <p>In addition to the basic informed consent process, participants will be engaged through a dedicated digital application developed as part of the project. The application will serve as a platform for ongoing communication, provision of relevant study-related information, and collection of feedback, where applicable. All interactions via the application will be clearly explained in the informed consent form, and participants will have full control over their engagement and data sharing.</p> <p>The results of the project will be disseminated through scientific publications, conference presentations, and communication channels targeting both the scientific community and the general public. While the project aims to ensure transparency and wide accessibility of its findings, the final test developed as part of the project will be made available exclusively as a commercial product and is not intended to be integrated into public healthcare systems at this stage.</p>
Research Setting and Duration	Setting: Genos research laboratory, Borongajska cesta 83H, 10 000 Zagreb, Croatia. Duration: 18 months.
Expected Outcomes and Ethical Considerations.	<p>Expected Outcomes: The primary outcome is a novel "GlycoCardio test," a tool for personalized CVD risk management. This includes the development of a dedicated app for end-users. If successful, the test is expected to be licensed to the partner company GlycanAge Ltd. and offered through its global network of over 500 clinical partners, with an ultimate goal of becoming a routine clinical diagnostic test. This is anticipated to reduce CVD morbidity and mortality.</p> <p>Ethical Considerations: The project commits to complying with the highest ethical standards, including relevant national, EU, and international legislation like the Helsinki Declaration and GDPR. The ethical approval from local or national ethics committees will be obtained for each conducted study. For all data and samples used, full patient consent will be obtained, ensuring patient confidentiality and data security. Patient data will be pseudonymized; the coordinating site will not hold any personally identifiable data. The project involves processing sensitive personal data, including genetic, biometric, and health data, which will be handled according to specific rules and the principle of data sparseness.</p> <p>Thus, all sensitive personal and health-related data, including IgG profiles and other biological information, will be processed in full compliance with GDPR. Technical and organizational measures will be implemented to ensure data security and confidentiality. These measures include pseudonymization of all samples and</p>

	<p>datasets and restricted access to data based on user role. No directly identifiable personal data will be shared outside the authorized research team. Data will be stored on secure infrastructure maintained by Genos in compliance with applicable data protection standards.</p>
LEGISLATION	<p>National and local regulations, relevant documents for the most important human studies in GlycoCardio</p> <ul style="list-style-type: none"> - Law on Protection of Patients' Rights, Official Gazette no. 169/04, 37/08 (Zakon o zaštiti prava pacijenata, Narodne novine br. 169/04, 37/08) - Law on Health Care, Official Gazette no. 100/18 (Zakon o zdravstvenoj zaštiti, Narodne novine br. 100/18) - Law on Medical profession, Official Gazette no. 121/03, 117/08 (Zakon o liječništvu, Narodne novine br. 121/03, 117/08) - Law on Blood and Blood Preparations, Official Gazette no. 79/06, 124/11 (Zakon o krvi i krvnim pripravcima, Narodne novine br. 79/06, 124/11) - Law on Application of Human Tissues and Cells, Official Gazette no. 144/12 (Zakon o primjeni ljudskih tkiva i stanica, Narodne novine br. 144/12) - Code of Medical Ethics and Deontology, Official Gazette no. 55/ - Act on the Right of Access to Information (OG 25/13, 85/15, 69/22) - Labor Act (OG 93/14, 127/17, 98/19, 151/22, 46/23, 64/23); - Gender Equality Act (OG 82/08, 69/17); - Anti-discrimination Act (OG 85/08, 112/12); <p>Relevant EU legislation and directives</p> <ul style="list-style-type: none"> - Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data. - Directive 2004/23/EC1 of the European Parliament and of the Council of 31 March 2004 setting standards of quality and safety for the donation, procurement, testing, preservation, processing, storage and distribution of human tissues and cells. - The EU Charter of Fundamental Rights; - Universal Declaration on the human genome and human rights adopted by UNESCO; - Helsinki Declaration (adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964; amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975; the 35th World Medical Assembly, Venice, Italy, October 1983; the 41st World Medical Assembly Hong Kong, September 1989; the 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996 and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000); - Principles enshrined in the Oviedo Bioethics Convention

	<ul style="list-style-type: none"> - ICH GCP, ICH:s guidelines for Good Clinical Practice http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html - EU Clinical Trials Directive (2001/20/EC), - EU General Data Protection Regulation 2016/679 (25.05.2018) - Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention)
PUBLIC CONSULTATION	
Identify when / where the public consultation process took place and what were the remarks from the consulted stakeholders	There was no formal public consultation process; the project is built upon extensive internal research and scientific discovery conducted by Genos. The direction and goals are based on the team's long-standing expertise and previous findings in this specific field.
INSTITUTIONAL CAPACITY BUILDING	
Will there be any capacity building?	<p>YES</p> <p>Although Genos has solid scientific and laboratory expertise, we have identified several areas where additional capacity building is needed. In particular, the team has limited experience with World Bank ESF requirements and DIGIT-specific procedures, and some of our existing biosafety, OHS and waste management practices need to be better documented and aligned with project-specific monitoring and reporting. In addition, we see a need to strengthen our understanding of GDPR and data protection.</p> <p>As part of this process, we will also prepare and formally adopt short written SOPs, checklists and templates, and provide on-the-job guidance to junior staff. This will help us systematically address the identified gaps and ensure that environmental, social, health and safety aspects are managed consistently throughout implementation.</p>
ATTACHEMENTS	
	 Informed consent draft.docx - Draft of Informend consent

Part II - Environmental/Social screening

PART 2: ENVIRONMENTAL /SOCIAL SCREENING

Will the site activity include / involve any of the following potential issues / risks:	Activity	Status	Additional references
	A. Social risk management <ul style="list-style-type: none"> • Ethical Compliance • Informed Consent and Voluntary Participation • Privacy, Data Protection and Confidentiality • Benefit Sharing and Fairness • Management of Findings and Traceability • Intellectual Property Management • Dissemination • Grievance Redress Mechanism 		See Section A
	B. Environmental risk management <ul style="list-style-type: none"> • Generation of waste • Sustainable Laboratory Practices • Green Procurement and Materials • Use of energy resources • Sustainable Research Design 	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	If “Yes”, See Section B below
	C. Occupational health and safety <ul style="list-style-type: none"> • PPE • Handling and storage of plasma • Hygiene 	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	If “Yes”, See Section C below
	D. Other issues, not mentioned above (e.g. AI related)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If “Yes”, See Section D below

Mitigation measures

- A. General conditions and social risk management
- B. Social risk management
- C. Environmental risk management
- D. Other issues

Part III - Environmental and social mitigation measures

Activity	Parameter	Mitigation measures checklist
A Social risk management	Ethical Compliance and Legal Framework	<ul style="list-style-type: none"> a) Project activities shall comply with the ethical provisions outlined in the Code of Ethics and uphold the highest ethical standards. b) International, EU, and national laws, particularly EU Directive 2004/23/EC, shall be applied during project-related research activities. c) All necessary accreditation, designation, authorization, and licensing for the collection, use, or storage of human tissues and cells shall be obtained. d) The collection, storage, and use of human tissues shall comply with local, national, and international regulations. e) If cells and tissues are transferred to or from non-EU countries, compliance with EU Directive 2004/23/EC and data transfer regulations shall be ensured.
	Informed Consent and Voluntary Participation	<ul style="list-style-type: none"> f) Free, prior and fully informed consent from all donors shall be obtained, with special attention to vulnerable groups (e.g., patients, minorities, discriminated individuals). g) Consent protocols must be in full compliance with EU Regulation 536/2014 and the General Data Protection Regulation (GDPR). h) Participation in research shall be entirely voluntary and documented informed consent shall be obtained in advance. i) Donors shall have the right to withdraw consent and request the destruction of their samples. j) Documentation shall confirm that consent covers both primary and secondary use of samples, data sharing, storage duration, and destruction upon withdrawal of consent
	Privacy, Data Protection and Confidentiality	<ul style="list-style-type: none"> k) Confidentiality of personal data shall be ensured, and tissue samples shall be anonymized or de-identified. l) Data associated with human samples must be de-identified or anonymized before transfer and processing, in full compliance with GDPR and national regulations.
	Benefit Sharing and Fairness	<ul style="list-style-type: none"> m) Donors' cultural and religious beliefs shall be respected in relation to tissue donation and use.
	Management of Findings and Traceability	<ul style="list-style-type: none"> n) Procedures for handling unexpected or incidental findings shall be defined, including how participants will be informed and their right not to know.

Activity	Parameter	Mitigation measures checklist
B Environmental risk management		<ul style="list-style-type: none"> <li data-bbox="983 260 2039 323">o) The origin of human tissue and cell samples shall be clearly documented, including those from commercial sources, biobanks, or other institutions. <li data-bbox="983 323 1792 361">p) Validation in Real-World Settings shall be clearly documented.
	Intellectual Property Management	<ul style="list-style-type: none"> <li data-bbox="983 371 1994 434">q) Identifying and implementing appropriate protection measures such as copyright registration, trade secrets, or patents, where applicable.
	Dissemination	<ul style="list-style-type: none"> <li data-bbox="983 482 1949 577">r) Open science practices will be applied whenever appropriate to support early dissemination and transparency, while ensuring that sensitive or potentially exploitable project outputs are protected prior to release.
	Grievance Redress Mechanism (GRM)	<ul style="list-style-type: none"> <li data-bbox="983 593 2039 720">s) Grievance Redress Mechanism (GRM) shall be established by providing and publishing on the website e-mail address where the interested public, either groups or individuals, could send complaints, comments and/or suggestions. The e-mail address shall be reported to the DIGIT GRM of the CSF at grmdigit@hrzz.hr <li data-bbox="983 720 2039 847">t) Information on such received complaints, comments, and suggestions should be archived in a logical framework database and reported to the DIGIT Project GRM of the CSF on a monthly basis, together with information on the measures taken following received complaints, comments, and/or suggestions
	Internal Procedure for Reporting of Irregularities	<ul style="list-style-type: none"> <li data-bbox="983 895 2039 1022">u) The adopted regulation on the procedure for internal reporting of irregularities and the method of appointing a confidential person and the protection of whistleblowers shall be published one the website with the reporting instructions.
C Research integrity	Sustainable Laboratory Practices	<ul style="list-style-type: none"> <li data-bbox="983 1037 2016 1101">a) Energy-efficient technologies such as LED lighting, energy-saving equipment, and modern HVAC systems shall be implemented to reduce energy consumption. <li data-bbox="983 1133 2016 1196">b) The use of hazardous chemicals shall be minimized, and safer alternatives shall be explored. <li data-bbox="983 1196 2016 1260">c) Energy-efficient laboratory equipment (e.g., centrifuges, incubators, freezers) shall be used without compromising research quality.
	Waste Management	<ul style="list-style-type: none"> <li data-bbox="983 1275 2016 1371">d) Strict waste segregation protocols shall be implemented to separate hazardous from non-hazardous waste. All types of waste, including hazardous waste, will be collected by licensed waste collectors and subsequently disposed of or treated at

Activity	Parameter	Mitigation measures checklist
		<p>authorized landfills and processing facilities specialized for each waste category. The disposal of infectious waste without prior neutralization treatment is strictly prohibited. Any replaced equipment classified as electronic waste will be collected by certified e-waste handlers.</p> <ul style="list-style-type: none"> e) Single-use plastic items shall be replaced with reusable or biodegradable alternatives where possible. f) Hazardous biomedical waste shall be disposed of through licensed waste management contractors.
	Green Procurement and Materials	<ul style="list-style-type: none"> g) Reusable lab tools and equipment (e.g., glassware) shall be used whenever feasible to minimize disposable waste.
	Reduction of Water Usage and Wastewater management	<ul style="list-style-type: none"> h) Water-efficient laboratory practices shall be implemented, including water-saving equipment and process water recycling. i) Liquid waste will not be released to the drain before the treatment. Discharged water will meet requirements of the Ordinance on Wastewater Emission Limit Values
	Researcher Training and Awareness	<ul style="list-style-type: none"> j) Continuous training for researchers and lab staff on environmental best practices shall be provided. k) Awareness within the research community about the environmental impacts of biomedical research shall be promoted. l) Laboratory staff with medical conditions or pregnant will not participate or work with chemicals that can aggravate their condition.
	Compliance and Alternatives	<ul style="list-style-type: none"> m) Research activities shall comply with a local, national, and international environmental regulations.
C Occupational health and safety	Risk Assessment and Biosafety	<ul style="list-style-type: none"> a) Risk assessment shall be conducted to identify potential biological hazards associated with human plasma. Risk assessment will be carried out for all staff positions.
	Indoor air quality	<ul style="list-style-type: none"> b) The laboratory will be well aired and digestors used where/when required (release of gassess is possible).

Activity	Parameter	Mitigation measures checklist
	Emergency procedures	c) Safety, alerting and emergency procedures are developed for staff and community, are communicated to staff and diligently followed.
	Working procedures	d) Working procedures are clear and available to all staff. Laboratory is licensed and accredited in accordance with the law.
	Personal Protective Equipment (PPE)	e) Appropriate PPE (e.g. but not limited to lab coats, gloves, goggles, face shields, masks/respirators) must be provided and shall be worn by all personnel. f) PPE shall be regularly inspected, properly maintained, and safely disposed of after use.
	Handling and Storage of Plasma	g) All plasma samples must be treated as potentially infectious, following universal precautions. h) Plasma samples shall be stored in clearly labeled, secure, and temperature-controlled storage. i) The use of sharps shall be minimized, and injury prevention measures must be implemented.
	Decontamination and Disinfection	j) Laboratory surfaces and equipment must be disinfected before and after use with approved disinfectants. k) Reusable instruments must be sterilized using autoclaves or validated decontamination procedures.
	Hygiene and Laboratory Practices	l) Hands must be washed thoroughly with soap and water after handling samples or removing gloves. m) Eating, drinking, smoking, and cosmetic application are to be prohibited in laboratory areas. n) Access to laboratories must be restricted to trained and authorized personnel.
	Emergency Preparedness and Incident Response	o) Spill response kits and emergency eyewash stations must be made available in all laboratory spaces. p) Staff must be trained to respond to spills and accidents, including containment, disinfection, reporting, and medical response.

Activity	Parameter	Mitigation measures checklist
		<ul style="list-style-type: none"> q) Emergency procedures and contact details must be clearly posted, and exits must be marked and kept accessible
	Health Surveillance and Protection	<ul style="list-style-type: none"> r) Exposure incidents must be managed according to post-exposure protocols, and medical treatment must be provided immediately.
	Training and Awareness	<ul style="list-style-type: none"> s) All staff handling human plasma must be trained in biosafety practices, proper PPE usage, and waste management. t) Refresher trainings must be conducted regularly and attendance must be documented.
	Biomedical Waste Management	<ul style="list-style-type: none"> u) Biomedical waste, including used PPE and plasma-contaminated materials, must be disposed of in clearly labeled biohazard containers. v) Licensed contractors must be engaged for the collection, transport, and final treatment of hazardous medical waste.
	Monitoring and Compliance	<ul style="list-style-type: none"> w) Regular inspections and audits must be performed to ensure compliance with OHS and biosafety requirements. x) A designated OHS/biosafety officer must be appointed to oversee implementation and adherence to safety protocols.
D Other issues, not mentioned above	(e.g. AI related)	<ul style="list-style-type: none"> a) Implement Code of Ethic for the preparation and implementation of the projects funded by the DIGIT Project

MONITORING PLAN

(The monitoring plan should include: purpose of monitoring, parameters to be monitored, monitoring methods and frequency, responsibilities, reporting and documentation, corrective actions, and monitoring tools and resources.)

Monitoring Plan: Social risk management, Environmental Risk Management and Occupational Health and Safety

Purpose of Monitoring

The purpose of monitoring under this ESMP is to ensure that social risk management, environmental protection and occupational health and safety measures are effectively implemented throughout the lifecycle of the project. The monitoring activities aim to verify compliance with applicable local, EU, and international standards (including World Bank safeguards), ensure that mitigation measures are practically enforced, and provide early identification of non-compliance to allow for timely corrective actions. Both Genos and GlycanAge are fully committed to implementing the following measures that will be part of the implementation of the activities of this project. GlycanAge will sign a declaration of compliance with the measures (related to GlycanAge) from this list and which will be valid for the implementation of this project. Since GlycanAge is a partner company affiliated with Genos, cooperation in the implementation of the project is fully ensured.

Ethics Committee shall be formed before implementation of activities.

Tasks of the Ethics Committee in the Project: "IgG Glycome Composition as a Biomarker for Personalised Prevention and Management of Cardiovascular Diseases"

Given that this project involves **human participants**, **biomedical research**, and **sensitive data** (biological samples, health-related and personal information), the Ethics Committee will have several important responsibilities. These include:

1. Review of Informed Consent Procedures

- Ensure that all informed consent forms:

- Are clear, understandable, and comprehensive.
- Clearly describe the study's purpose, methods, risks, and participant rights.
- Emphasize voluntary participation and the right to withdraw at any time.

2. Assessment of Biological Sample Collection and Use (e.g., blood)

- Ensure that:
 - Samples are collected ethically and safely.
 - Participants are fully informed about how their samples will be used.
 - Samples are not used for purposes beyond the scope of the study without additional consent.

3. Protection of Personal and Health-Related Data (GDPR Compliance)

- Review the plans for:
 - Anonymization or pseudonymization of data.
 - Secure storage and handling of health and genetic information.
 - Restriction of access to data only to authorized personnel.

4. Risk-Benefit Assessment

- Evaluate:
 - Whether the study poses any physical, psychological, or emotional risks to participants.
 - Whether the potential scientific or societal benefits outweigh those risks.
 - What measures are in place to minimize potential harm.

5. Issuing Ethical Approval

- The Ethics Committee must:
 - Review and approve the study protocol before any data or sample collection begins.
 - Approve all study-related documents (e.g., protocols, consent forms, information sheets).

6. Monitoring During Project Implementation

- The Committee may request:
 - Regular progress reports.
 - Notification of unexpected events (e.g., data breaches, participant complaints).
 - Amendments to the protocol if substantial changes occur.

7. Advisory Role

Provide guidance to the research team in case of ethical dilemmas or necessary adjustments to the study procedures.

1. Activity A: Social risk management

1.1. Ethical Compliance and Legal Framework

Project activities shall comply with the ethical provisions outlined in the Code of Ethics and uphold the highest ethical standards. International, EU, and national laws, particularly EU Directive 2004/23/EC, shall be applied during project-related research activities. All necessary accreditation, designation, authorization, and licensing for the collection, use, or storage of human tissues and cells are secured. The collection, storage, and use of human tissues shall comply with local, national, and international regulations. If cells and tissues are transferred to or from non-EU countries, compliance with EU Directive 2004/23/EC and data transfer regulations shall be ensured. GlycanAge's main task is to provide samples for research to be conducted at Genos, so monitoring will be mainly focused on the code of ethics and data security.

1.2. Informed Consent and Voluntary Participation

Free, prior and fully informed consent from all donors shall be obtained, with special attention to vulnerable groups (e.g., patients, minorities, discriminated individuals). Consent protocols must be in full compliance with EU Regulation 536/2014 and the General Data Protection Regulation (GDPR). Participation in research shall be entirely voluntary and documented informed consent shall be obtained in advance. Donors shall have the right to withdraw consent and request the destruction of their samples. Documentation shall confirm that consent covers only primary use of samples, data sharing, storage duration, and destruction upon withdrawal of consent. There will be no secondary use of samples. A sample informed consent form is attached and will be fully prepared by the Ethics Committee of Genos and GlycanAge Ltd. Samples will be destroyed or stored securely with no further use unless new consent is obtained.

Existing samples – source and type:

The existing samples include human plasma and immunoglobulin G isolated from either plasma or blood stains, previously collected within research projects conducted by GlycanAge Ltd and other partners. The samples are pseudonymised and were collected with prior informed consent.

Samples to be collected – source and type:

During the project, additional blood and plasma samples will be collected from the general population and targeted groups (e.g., women in menopause) who underwent specific dietary, pharmacological or lifestyle interventions. The samples will be pseudonymised, and the collection procedures will be conducted in accordance with ethical guidelines and informed consent.

1.3. Privacy, Data Protection and Confidentiality

Conducts: Genos and GlycanAge

Confidentiality of personal data shall be ensured, and tissue samples shall be anonymized or de-identified as always when samples are collected for any research. Due diligence shall be conducted to verify the original purpose and consent conditions under which third-party samples were collected. Data associated with human samples must be de-identified or anonymized before transfer and processing, in full compliance with GDPR and national regulations.

Also, a sample of informed consent form is attached and will be fully prepared by the Ethics Committee of Genos and GlycanAge Ltd.

Personal data will be used exclusively for research purposes, in compliance with the GDPR, with strict access controls applied throughout the project. All data are pseudonymised, and analyses are conducted on aggregated data. Also, no data that could lead to the identification of individual participants will be published or shared, and all results will be published exclusively in aggregated form, ensuring that individual identities remain fully protected.

Informed consent for collected samples:

Consent was obtained within the framework of previous research projects. Participants were informed about the purpose of the research, storage, and the use of data and samples, including glycomics analysis.

Informed consent for future samples:

New samples will be collected only with signed informed consent, in full compliance with all ethical and legal requirements. Participants will be informed about all aspects of participation and data use with specific emphasis on their risks and potential benefits.

1.4. Benefit Sharing and Fairness

Conducts: Genos and GlycanAge

Donors' cultural and religious beliefs shall be respected in relation to tissue donation and use.

The project will ensure equitable access to benefits resulting from research outcomes, including potential commercial applications.

1.5. Management of Findings and Traceability

Conducts: Genos and GlycanAge

The origin of human tissue and cell samples shall be clearly documented, including those from commercial sources, biobanks, or other institutions if applicable. Validation in Real-World Settings shall be clearly documented.

Existing samples – source and type:

The existing samples include human plasma and immunoglobulin G isolated from either plasma or blood stains, previously collected within research projects conducted by GlycanAge Ltd and other partners. The samples are pseudonymised and were collected with prior informed consent.

Samples to be collected – source and type:

During the project, additional blood and plasma samples will be collected from the general population and targeted groups (e.g., women in menopause) who underwent specific dietary, pharmacological or lifestyle interventions. The samples will be pseudonymised, and the collection procedures will be conducted in accordance with ethical guidelines and informed consent.

1.6. Intellectual Property Management

Conducts: Genos

Identifying and implementing appropriate protection measures such as copyright registration, trade secrets, or patents, where applicable.

1.7. Dissemination

Conducts: Genos and GlycanAge

Open science practices will be applied whenever appropriate to support early dissemination and transparency, while ensuring that sensitive or potentially exploitable project outputs are protected prior to release.

Dissemination of results:

Project results will be disseminated through scientific publications, scientific conferences (posters and presentations), social media, newsletters, educational events, and webinars. Activities aimed at popularising science for the general public are also planned.

Role of GlycanAge Ltd in project implementation:

GlycanAge Ltd plays a key role in sample collection through its network of clinical partners. Also, it will be involved in biomarker validation, data integration, and evaluation of commercial potential through on-going studies related to different interventions (lifestyle or pharmacological). Additionally, it will be involved in the development of GlycoCardio test and dissemination activities at different longevity conferences.

1.8. Grievance Redress Mechanism (GRM)

Conducts: Genos and GlycanAge

Grievance Redress Mechanism (GRM) shall be established by providing and publishing on the website e-mail address where the interested public, either groups or individuals, could send complaints, comments and/or suggestions. The e-mail address shall be reported to the DIGIT GRM of the CSF at grmdigit@hrzz.hr. Information on such received complaints, comments, and suggestions should be archived in a logical framework database and reported to the DIGIT Project GRM of the CSF on a monthly basis, together with information on the measures taken following received complaints, comments, and/or suggestions.

ACTION PLAN

Project duration: 18 months

Purpose: To provide a transparent, confidential, and effective mechanism for reporting and resolving ethical and safety issues related to project implementation, in accordance with applicable national and international ethical standards and HRZZ guidelines

Step	Description	Genos	GlycanAge
1. Complaint Submission	<p>Complaints are submitted via official project email and forwarded to HRZZ.</p> <p>Scope of complaints:</p> <ul style="list-style-type: none">• Ethical misconduct (e.g., violation of participants' rights)• Safety or security incidents• Breaches of confidentiality or data protection• Inappropriate behaviour by project staff or associates	Maintains GRM email; ensures visibility of mechanism.	Informs team about the GRM channel; forwards any complaints.
2. Confidentiality & Protection	Complaints can be submitted anonymously. If the identity of the complainant is known, it is handled confidentially. No negative consequences shall arise for individuals who report in good faith.	Ensures GDPR compliance and secure handling.	Handles complaints confidentially; communicates securely with lead.
3. Logging &	Complaints are stored in a database and categorized.	Maintains central database; tracks	Records local complaints and

Step	Description	Genos	GlycanAge
Classification		status and actions.	shares them with lead.
4. Analysis & Measures	Complaints are assessed; actions taken (e.g., protocol change, warnings). Ethics committees, experts, or HRZZ may be consulted if necessary.	Coordinates analysis and response; documents actions.	Participates in analysis when concerns its activities; applies corrective actions locally.
5. Reporting to HRZZ	Reports sent every month to grmdigit@hrzz.hr .	Prepares and submits consolidated reports.	Provides data and updates from their institution.

Social risk management MONITORING PLAN

#	Activity	Monitoring Frequency	Responsibility	Measures	Source of verification	Monitoring indicator	Implementation status and description
1	Informed consent process and ethical counselling	100% prior to enrolment	Project team	Informed consent process and ethical counselling	Internal Report	Documented Risk Assessment and Biosafety	
2	Digital application for communication and feedback	Quarterly	Project team	Digital application for communication and feedback	App usage statistics	Number of participants actively using the digital application	
3	Grievance Redress Mechanism (GRM)	Monthly	Project team	Grievance Redress Mechanism (GRM)	GRM database records	Number and proportion of grievances received and resolved via GRM	
4	Dissemination of results (scientific and public)	After completion of analyses and validation; during and after project	Project team	Dissemination of results (scientific and public)	Dissemination reports	Number of dissemination activities (publications, conferences, public events)	
5	Communication and data sharing	End of project	Project team	Communication and data sharing	Structured questionnaires	Participant satisfaction level (via survey in the app)	

2. Activity B: Environmental Risk Management

2.1. Sustainable Laboratory Practices

Conducts: Genos and GlycanAge

Yearly inspections are generally carried out, more often if necessary, to verify the use of energy-efficient technologies (e.g., LED lighting, efficient HVAC systems) and energy-saving equipment (e.g., centrifuges, incubators). The Lab Managers are responsible for ensuring compliance. Any inefficiencies trigger corrective actions such as upgrading equipment or modifying usage protocols.

2.2. Waste Management

Conducts: Genos and GlycanAge

Weekly visual inspections are usually conducted to ensure waste segregation protocols are followed, separating hazardous from non-hazardous waste.

Monthly reviews of waste logs and contractor disposal receipts can verify proper biomedical waste handling. The Lab Managers are responsible. In case of mismanagement, staff is retrained, and storage systems are always upgraded.

1. Laboratory Waste Management

We confirm that hazardous chemical, biological, and plastic waste will be generated during laboratory activities. The following measures will be implemented:

a. Waste Classification and Segregation

Waste will be categorized as hazardous or non-hazardous in accordance with national legislation (e.g., Croatian Law on Sustainable Waste Management, OG 94/13) and EU Waste Framework Directive (2008/98/EC).

Waste categories include:

Biological waste (e.g., plasma-contaminated materials)

Chemical waste (e.g., enzymes, labeling agents)

Sharps and PPE

Plastic and non-hazardous waste (e.g., packaging)

b. Storage and Labeling

Hazardous waste will be stored in clearly labeled, sealed containers in designated areas. Separate storage areas will be designated for chemical, biomedical, and plastic waste. Material Safety Data Sheets (SDSs) will be available for all hazardous materials stored on site.

c. Transportation and Disposal

All hazardous waste will be disposed of via licensed and certified waste contractors. Transportation and disposal will comply with: National hazardous waste

transport rules. Best practices from UN Basel Convention.

d. Hazardous Materials Management Plan

A Hazardous Materials Management Plan (HMMP) will be implemented, which includes:

Safe storage guidelines.

Use of SDSs for all chemicals.

Emergency spill response procedures.

Regular training for lab staff.

Dedicated Chemical Safety Officer (as part of OHS team).

2. Chemicals and Reagents: Use and Storage

The project involves use of: Enzymes, antibodies, labeling agents, and other standard molecular reagents.

Measures for safe use and storage: Chemicals will be stored in locked, ventilated cabinets based on hazard class. Enzymes and temperature-sensitive reagents will be kept in monitored cold storage (2–8°C or –20°C).

All containers will be clearly labeled with:

Chemical name

Concentration

Hazard classification

SDSs will be accessible digitally and in hard copy.

Training sessions on chemical handling and emergency procedures will be conducted semi-annually.

3. Resource Consumption and Minimization

No higher consumption of water and electricity is expected compared to previous projects and usual activities in the research laboratory.

Lab Materials

Disposable plastics (tips, tubes) use minimized via: Reusable glassware where applicable. Switching to biodegradable plastics when available.

2.3. Green Procurement and Materials

Conducts: Genos

Reusable lab tools and equipment (e.g., glassware) shall be used whenever feasible to minimize disposable waste.

2.4. Reduction of Water Usage

Conducts: Genos and GlycanAge

Monthly reviews of utility bills and biannual audits of water-efficient equipment will be conducted by the Facilities Officer. Closed-loop water systems and recycling technologies can not be introduced due to the nature of a work itself.

2.5. Researcher Training and Awareness

Conducts: Genos

All researchers and lab staff will participate in internal biannual training sessions on environmental best practices. Pre- and post-training assessments will be conducted, and participation will be recorded.

2.6. Compliance and Alternatives

Conducts: Genos

An annual audit will confirm that the research complies with all relevant environmental legislation

Activity C: Occupational Health and Safety (OHS)

B Environmental risk management MONITORING PLAN

#	Activity	Monitoring Frequency	Responsibility	Measures	Source of verification	Monitoring indicator	Implementation status and description
2.1	Sustainable Laboratory Practices	Annually (more frequently if needed)	Facilities Manager	Implementation of energy-efficient technologies such as LED lighting, energy-saving equipment, and modern HVAC systems to reduce energy consumption.	Internal Report on Energy Consumption	Number and type of energy-efficient technologies installed	
			Lab Safety Officer	Minimal use of hazardous chemicals.	Updated Chemical Inventory	Types and quantities of hazardous chemicals replaced	
			Lab Manager	Use of energy-efficient laboratory equipment (e.g., centrifuges, incubators, freezers).	Equipment Inventory	Number and type of energy-efficient equipment in use	
2.2	Waste Management	Genos, GlycanAge Weekly visual	Lab Managers	Enforcement of strict waste segregation (hazardous vs non-hazardous).	Waste Management Report	Documented waste segregation procedures and audit reports	

#	Activity	Monitoring Frequency	Responsibility	Measures	Source of verification	Monitoring indicator	Implementation status and description
		checks; monthly log & receipt reviews	Procurement Officer	Use reusable/biodegradable items where possible	Consumables Usage Report	Percentage reduction in plastic use; inventory of reusable items	
			Lab Managers	Contract licensed biomedical-waste disposal contractors	Waste management logs	Contractor licenses and disposal manifests	
2.3	Green Procurement and Materials	Genos Ongoing (where feasible)	Procurement Officer	Use reusable lab tools and equipment (e.g., glassware) whenever feasible to reduce disposable waste	Internal Record of Procurement and Use	Inventory of reusable tools and frequency of use	
2.4	Reduction of Water Usage	Genos, GlycanAge Monthly utility reviews; biannual audits	Facilities Officer	Implement water-efficient practices (low-flow taps, process-water recycling)	Invoices / Water Consumption Analysis	Reduction in monthly water consumption (liters) compared to baseline level.	
				Install and maintain water-saving equipment (e.g., sensor taps, closed-loop systems)			
2.5	Researcher Training and Awareness	Genos Biannual internal training sessions	Training Coordinator	Continuous training on environmental best practices for all researchers & staff	Training Records	Training sessions held; attendance records	
				Promoting awareness of biomedical research's	Internal Report	Outreach materials	

#	Activity	Monitoring Frequency	Responsibility	Measures	Source of verification	Monitoring indicator	Implementation status and description
				environmental impacts		developed; feedback collected	
2.6	Compliance and Alternatives	Genos Annual compliance audit	Compliance Officer	Ensure all research activities comply with local, national, and international environmental regulations	Compliance Report / Inspection Findings	Inspection reports; regulatory compliance certifications	

3. C Occupational health and safety

Organizational Structure for OHS

- a) Employer (Genos LTD/Gordan Lauc, PhD) holds ultimate responsibility for OHS, allocates resources, appoints responsible persons, and ensures legal compliance.
- b) OHS Specialist (Ana Savanović, eng. chem.) is a designated external professional who manages OHS tasks, including monitoring, training, and risk assessments.
- c) OHS Coordinator (Helena Deriš, mag. pharm.) is a designated employee who micromanages day-to-day OHS tasks and is the direct link between OHS Specialist and employees.
- d) OHS Committee is a safety committee that meets once every six months and is formed to ensure participation of workers in OHS planning and decision-making. Its members are:
 1. Svjetlana Bušić, mag. oec. – Chair of the committee, COO
 2. Ana Savanović, eng. chem. – external OHS Specialist
 3. Helena Deriš, mag. pharm. – internal OHS Coordinator, Researcher
 4. Karolina Šimić Marinović, dr. med. – external Occupational Medicine Specialist

3.1. Risk Assessment and Biosafety

Conducts: Genos and GlycanAge

Prior to the start of research, a full biosafety risk assessment will be conducted to identify new potential hazards related to plasma handling. This assessment will be reviewed annually.

3.2. Personal Protective Equipment (PPE)

Conducts: Genos and GlycanAge(if possible)

Daily checks will confirm that all personnel are equipped with appropriate PPE. Monthly inventory audits will track stock levels, and any deficiencies will prompt immediate resupply or retraining.

Procedures:

1. Use of Standard Operating Procedures (SOPs) for laboratory work.
2. Chemical and biological handling protocols.
3. Emergency response plans, including fire and chemical spill procedures.
4. Waste disposal procedures (chemical and biological).
5. Ventilation control and air monitoring in high-risk areas.

PPE includes:

1. Laboratory coats and protective clothing.
2. Gloves (nitrile, latex depending on substance).
3. Safety goggles and face shields.
4. Respirators or masks when dealing with aerosols or volatile substances.
5. Hearing protection when working with noisy equipment.
6. Closed footwear resistant to chemicals .

3.3. Handling and Storage of Plasma

Conducts: Genos and GlycanAge

All plasma will be treated as potentially infectious and stored in secure, temperature-controlled, clearly labeled containers. Daily checks and weekly reviews of storage logs will ensure compliance.

3.4. Decontamination and Disinfection

Conducts: Genos and GlycanAge

All laboratory surfaces will be disinfected before and after use, and reusable instruments will be sterilized using validated methods. Compliance will be monitored through daily cleaning logs.

3.5. Hygiene and Laboratory Practices

Conducts: Genos and GlycanAge

Strict hygiene practices will be enforced, including regular handwashing and prohibition of food or cosmetic use in labs. Access to labs will be restricted to trained personnel.

3.6. Emergency Preparedness and Incident Response

Conducts: Genos and GlycanAge

Emergency kits and eyewash stations are generally checked monthly. Biannual emergency response drills will be conducted to train staff on containment, disinfection, and medical response.

1. Chemical Spill or Contamination Incident:

- Immediately alert all personnel in the affected area.
- Evacuate non-essential staff to a safe distance.
- Don appropriate PPE before approaching the spill area.
- Contain the spill using available spill kits (absorbent pads, neutralizers).
- Follow the Material Safety Data Sheet (MSDS) instructions for specific chemicals.
- Dispose of contaminated materials in designated hazardous waste containers.
- Report the incident to the Laboratory Safety Officer and complete an incident report.

2. Injury Response:

- Provide immediate first aid or medical assistance as needed.
- If necessary, activate emergency medical services (EMS) by calling the designated emergency number.
- Use eyewash stations or safety showers for chemical exposures.
- Document the injury details and report to Occupational Health and Safety Officer.
- Review the incident to identify root causes and implement preventive measures.

3. Emergency Communication:

- Ensure emergency contact numbers are posted and accessible.
- Train staff on how to use emergency alarms and communication tools.
- Conduct regular emergency drills to ensure preparedness.

All the identified risks and ways to address them are listed in the Genos - Risk Assessment Document from 2018. The document identifies several types of workplace risks, including:

1. Mechanical hazards: such as injuries from machinery or sharp objects.
2. Chemical hazards: due to the use of various chemicals in laboratory settings (e.g., ethanol, chloroform, acetone).
3. Biological hazards: especially when working with biological samples or infectious materials.
4. Fire and explosion risks: particularly from flammable chemicals and electrical equipment.
5. Ergonomic risks: like prolonged standing or repetitive tasks.
6. Psychosocial risks: such as stress due to workload or organizational changes.

Risk control measures include:

1. Performing risk assessments for each specific task.

2. Maintaining safety data sheets (SDS) for all hazardous chemicals.
3. Using appropriate ventilation and fume hoods.
4. Regular servicing of equipment.
5. Safe storage and disposal of chemicals and biological material.
6. Ensuring electrical installations are certified and safe.
7. Implementing organizational policies to prevent work overload and stress.

3.7. Health Surveillance and Protection

Conducts: Genos and GlycanAge

All exposure incidents will be managed using approved post-exposure protocols. Immediate medical attention will be provided.

3.8. Training and Awareness

Conducts: Genos and GlycanAge

Annual training sessions will be held for all staff on biosafety practices, proper PPE usage, and biomedical waste management. Attendance will be logged. OHS induction training tailored to the specific roles is provided to all the new hires. Regular OHS training is also provided to all the employees changing their roles internally. Records of all training activities are documented. OHS Coordinator ensures the use of signage, posters, and briefings to keep safety top of mind.

3.9. Biomedical Waste Management

Conducts: Genos and GlycanAge

Biomedical waste is collected in biohazard-labeled containers and handled by licensed contractors. Weekly inspections and monthly audits are performed by Lab Managers and Occupational Health and Safety Officers.

3.10. Monitoring and Compliance

Conducts: Genos

Monthly OHS inspections and an annual safety audit will be carried out. The OHS Officer will maintain detailed inspection records and oversee corrective measures for any violations.

Occupational Health and Safety MONITORING PLAN

#	Activity	Monitoring Frequency	Responsibility	Measures	Source of verification	Monitoring indicator	Implementation status and description
3.1	Risk Assessment and Biosafety	Annually (more frequently if needed)	Internal OHS officer	Conduct full biosafety risk assessments to identify potential biological hazards associated with human plasma	Internal Report	Documented Risk Assessment and Biosafety	
3.2.	Personal Protective Equipment (PPE)	Genos, GlycanAge Daily visual checks; monthly log	Lab Managers	Provide and mandate use of appropriate PPE (coats, gloves, goggles, shields, masks/respirators)	Internal Report	Inventory of PPE	
			Lab Managers	Regularly inspect, maintain, and safely dispose of PPE after use	Internal Report	Inventory of PPE	
3.3	Handling and Storage of Plasma	Genos Ongoing (where feasible)	Lab Managers	Treat all plasma as potentially infectious, following universal precautions	Instructions for behavior in the laboratory	Number of recorded incidents in labs	
			Lab Managers	Store in clearly labeled, secure, temperature-controlled units	Instructions for behavior in the laboratory	Number of clearly labeled, secure, temperature controlled units	
			Lab Managers	Minimize sharps use & implement injury-prevention measures	Instructions for behavior in the laboratory	Number of recorded incidents in labs	

#	Activity	Monitoring Frequency	Responsibility	Measures	Source of verification	Monitoring indicator	Implementation status and description
3.4	Decontamination and Disinfection	Genos, GlycanAge Monthly utility reviews; biannual audits	Lab Managers	Disinfect surfaces & equipment with approved agents pre and post use	Instructions for behavior in the laboratory	Consumption of sterilizing agent	
			Lab Managers	Sterilize reusable instruments via autoclave or validated methods	Clearly separated sterilized from non-sterilized equipment	number of sterilization procedures	
3.5	Hygiene and Laboratory Practices	Continuously	Lab Managers	Enforce regular handwashing and PPE hygiene	Instructions for regular hand washing and personal protective equipment hygiene	Number of recorded incidents in labs	
			Lab Managers	Prohibit food, drink, smoking, cosmetics in labs	Signs prohibiting food, drinks and cosmetics in the laboratory	Number of recorded incidents in labs	
			Lab Managers	Restrict access to trained, authorized personnel	Signs prohibiting access to unauthorized	List of trained and authorized personnel	

#	Activity	Monitoring Frequency	Responsibility	Measures	Source of verification	Monitoring indicator	Implementation status and description
					personnel		
3.6	Emergency Preparedness and Incident Response	Monthly equipment checks; biannual drills	OHS Officer	Maintain spill kits & eyewash stations in all labs Train staff on spill/accident response (containment, disinfection, reporting, medical) Clearly post emergency procedures & keep exits accessible	Internal report Internal report Internal report	Number of Maintain spill kits and eyewash stations Attendance list Emergency preparedness	
3.7	Health Surveillance and Protection	As incidents occur	OHS Officer	Manage exposure incidents per approved post Exposure protocols with immediate medical treatment	Internal report Internal report	Number of incidents Number of incidents	
3.8	Biosafety Training and Awareness	Annual training sessions	OHS Officer	Train all plasma-handling staff in biosafety, PPE use, and environmental compliance	Internal report	Attendance list	

#	Activity	Monitoring Frequency	Responsibility	Measures	Source of verification	Monitoring indicator	Implementation status and description
				Conduct regular refresher courses and document attendance	Internal report	Attendance list	
3.9	Biomedical Waste Management	Weekly inspections; monthly audits	Lab Managers	Dispose of biomedical waste (used PPE, contaminated materials) in labeled biohazard containers	Waste management logs	Number of labeled biohazard containers	
			OHS Officer	Engage licensed contractors for collection, transport, and treatment	Waste management logs	Contractor licenses and disposal manifests	
3.10	OHS Monitoring and Compliance	Monthly OHS inspections; annual safety audit	OHS Officer	Perform regular OHS & biosafety inspections/audits	Internal report	Number of inspections/audits	
			OHS Officer	Appoint a designated OHS/biosafety officer to oversee protocol adherence	internal act	Name of internal OHS officer	

4. Reporting and Documentation

Internal reporting will occur monthly through structured logs and compliance summaries. Semi-annual reports will be submitted to the World Bank or other relevant funding bodies.

Incident reports will be submitted to the Project Implementation Unit (PIU) immediately, and not later than 24 hours, after any serious event which has, or is likely to have, a significant adverse effect on the environment, the affected communities, the public or workers. Incident reports will provide sufficient detail regarding the scope, severity, and possible causes of the incident or accident, indicating immediate measures taken or that are planned to be taken to address it. Reporting requirements will be in line with the Environmental and Social Commitment Plan (ESCP).

Training, audit, and inspection records will be archived for future reference and verification.

5. Corrective Actions

Corrective actions will vary based on the nature and severity of the non-compliance but may include: immediate retraining, equipment replacement, policy updates, supplier or contractor change, and escalation to ethics or oversight committees.

ANNEX Commitment letterGlycanAge Ltd

GlycanAge

The Catalyst
3 Science Square
Newcastle Helix
Newcastle Upon Tyne
England, NE4 5TG

To Whom It May Concern,

We are pleased to confirm our commitment to collaborating with Genos on the ERC-PoC project, GlycoCardio 2023.

Accordingly, we commit to implementing the mitigation list from the ESMP checklist and monitoring plan from the very beginning of the project implementation.

Sincerely,



Signed by:
002F728FD2384D0...

Nikolina Lauc
CEO, GlycanAge Ltd
8/18/2025