GreenME
Mental health for all through nature

D1.3.
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D1.3. Legal & Ethics Management handbook

Authors: Margarita Triguero-Mas (UOC), Helen Cole (UAB), Marta Cayetano (UAB), Susana Aragón (UAB), Paula de Prado-Bert (UAB), Silvio Caputo (UNIKENT)

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D1.3 Legal & Ethics management handbook

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Project n. 101084198

Advancing Greencare in Europe: an integrated multi-scalar approach for the expansion of nature-based therapies to improve mental health equity.

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1. Executive Summary

This handbook presents different strategies and procedures adopted within the GreenME project to comply with ethical and legal data protection requirements.

The first part of the document (i.e. section "2. Introduction") synthesizes the main aspects of GreenME that require particular attention in terms of ethical and data protection considerations.

The following section (i.e. "3. Ethical procedures") include the general recommendations and regulations that apply to GreenME and specify how these will be applied to the project.

Last, (i.e. "4. Data protection procedures") focus on the General Data Protection Regulation (GDPR) and how this will be applied in the GreenME project.

2. Introduction

Following ethical and data protection scientific practices is vital in all scientific research, particularly in those projects focusing on **underprivileged populations**. The GreenME project will involve **human participants** and collect and manage **personal data,** issues that need specific attention in following ethical procedures. One of the data protection issues that requires consideration in the GreenME project is that some of the personal data will be **transferred** from non-EU to EU countries, from non-EU to non-EU countries and from EU to non-EU countries. This last aspect will be covered in this document but also in the data management plan (DMP) that has been developed in parallel (D1.2. Data Management Plan, deliverable date: February 2024).

Another aspect of relevance to consider is that part of the human participants involved in GreenME are **underprivileged individuals (i.e. people with poor mental health and people from low socioeconomic status, ethnic/racial minorities, women).** We consider all these individuals as people from underprivileged populations because they are groups of people susceptible to harm or exploitation due to a lack of socioeconomic power or because they suffer social stigmatization. These underprivileged populations are also usually considered one of the vulnerable population groups. These participants will volunteer for public health and social sciences studies, and some of those with poor mental health will be included as patients for medical studies.

3. Ethical procedures

All HEurope project proposals have to fill in an ethics self-assessment. Then, during the evaluation phase for funding, projects above the threshold undergo an Ethics Review that ensures adherence of the projects to ethical principles and standards, pertinent

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European laws, agreements and declarations at international level, national authorizations, and ethical approvals. It also evaluates the appropriateness of research methods in relation to their proportionality and assesses the researchers' understanding of the ethical dimensions and societal implications of their proposed research. Ethics Reviews may lead to contractual obligations.

Following the usual process when applying to HEurope funding, during the GreenME proposal stage, the ethics self-assessment (including the ethics issues table that are divided in this document into two tables, section 3.3 & 4.3) was filled in. Then, during the evaluation phase for funding and as part of the evaluation that all projects above threshold undergo, GreenME went through an Ethics Review. This Ethics Review led to the requirements of appointing an Ethics Advisor (see section 3.4), which became part of GreenME contractual obligations with the European Commission, and also the requirement of establishing an ethics work package.

3.1. Research ethical framework and regulations

Research funded by the European Union is obliged to comply with ethical and moral principles, as set out in relevant codes of conduct such as the **European Code of Conduct for Research Integrity**. Research funded by the European Commission also must comply with relevant European, national, and international laws, including the **EU's Charter of Fundamental Rights** and the **European Convention on Human Rights** along with its Supplementary Protocols. Overall, the following fundamental principles must be respected in all research activities:

- The principle of proportionality → This principle implies that any actions or measures taken should be proportional to the intended goal. In the context of research, it suggests that the methods and interventions used should be appropriate and not excessive in relation to the objectives of the study.
- The right to privacy → The right to privacy ensures that individuals have the right to control their personal information and activities. In research, it means that participants' personal information should be handled with confidentiality and not disclosed without their consent.
- The right to the protection of personal data → Building on the right to privacy, this principle emphasizes the safeguarding of individuals' personal data. Researchers must take measures to protect and handle any collected personal data responsibly, adhering to data protection regulations.
- The right to physical and mental integrity of all individuals → This right asserts that individuals have the right to be free from any form of physical or mental harm. In the context of research, it requires that participants are not subjected to procedures or interventions that could cause harm to their physical or mental well-being.
- The right to equality and non-discrimination → This principle emphasizes that all individuals should be treated fairly and without discrimination. In research, it means that participants should be selected, recruited, and treated without bias, ensuring equal opportunities and representation.

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- High levels of protection for the environment and human health → This principle underscores the importance of safeguarding both the environment and the health of individuals. In research, it implies that studies should be conducted with measures in place to minimize any potential harm to the environment and prioritize the well-being of human participants.

The GreenME project involves human participants, i.e., humans are recruited, observed, and actively involved in the research process. Accordingly, GreenME will comply with existing ethical principles and national, EU and international legislation related to research conducted with humans.

3.1.1. Charter Of Fundamental Rights of the European Union

As mentioned in the previous section, GreenME project conducts research with human subjects, consequently the project needs to comply with national, EU and international legislation. The **Charter Of Fundamental Rights** is integrated into the legal framework of the European Union, and it plays a crucial role in ensuring the protection of fundamental rights. This document does not explicitly address research with humans, however, several fundamental rights within the Charter are relevant and can indirectly impact the ethical conduct of research involving human subjects.
Among the articles that will be considered for the implementation of the GreenME project we will focus on:

- Article 1. Human dignity: The right to human dignity is fundamental. This is interpreted to mean that research must respect the dignity of individuals and ensure that they receive ethical and respectful treatment. In addition, the dignity of the individual must be protected in all research decisions and activities.
- Article 3. Right to the integrity of the person: In the fields of medicine and biology, certain principles must be upheld, including the free and informed consent of the person concerned, according to the procedures laid down by law.
- Article 7. Respect for Private and Family Life: This article guarantees the right to respect for private and family life. In the context of research, it underscores the importance of respecting participants' privacy and ensuring the confidentiality of their personal information.
- Article 8. Protection of Personal Data: This article focuses specifically on exploring and discussing the fundamental right to the protection of personal data. It is highly relevant to research, emphasizing the importance of safeguarding individuals' personal data, requiring explicit, informed consent for data processing, and ensuring compliance with data protection regulations.
- Article 11. Freedom of Expression and Information: While this article is more broadly about freedom of expression, it may be relevant to different aspects of research that involve the dissemination of information. Researchers must consider this right when publishing and communicating research findings.
- Article 22. Cultural, Religious, and Linguistic Diversity: This article underscores the EU's commitment to cultural, religious, and linguistic diversity. Researchers

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should consider and respect the diversity of participants in their studies, acknowledging cultural and linguistic differences.
- Articles 10, 22, 26 and 37. These articles are related to: a) the freedom of thought, conscience and religion, b) the respect of cultural, religious and linguistic diversity, c) the respect and recognition of the right of persons with disabilities to benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community, and d) protection of the environment.

Specifically, as GreenME Project involves the dimension of health the Article 35, which concerns the right to health, needs also to be considered. It underscores the importance of ensuring that research activities contribute positively to the health and well-being of participants.

All the Charter articles are essential and significant when investigating underprivileged individuals in disadvantaged circumstances and vulnerable situations. It is important to protect the confidentiality and privacy of participants when collecting and handling sensitive information (Article 7), researchers must be especially diligent in protecting participants' personal data (Article 8) and ensure that individuals in a vulnerable situation (including underprivileged individuals) have access to adequate health care (Article 35). Furthermore, the principle of non-discrimination is crucial when working with vulnerable (including underprivileged) populations. Article 21 prohibits discrimination based on various grounds, including disability and other characteristics that might render individuals vulnerable. Researchers must ensure equal opportunities and fair treatment for all participants.

3.1.2. The European Convention on Human Rights (ECHR)

The ECHR is a treaty of the Council of Europe that also protects fundamental rights and freedom of individuals within Europe. While it does not specifically address research, several articles within the *ECHR* have implications for research involving human participants (as is the case of GreenME). Here are key points that are relevant to conduct research with human participants, and some of them are some of those advanced by the *Charter Of Fundamental Rights of European Union*:

- Article 8 - Right to Respect for Private and Family Life: This article safeguards the right to privacy. In research, it highlights the necessity of obtaining informed consent and ensuring the confidentiality and protection of participants' personal data.
- Article 2 - Right to Life: While primarily centred on the right to life, this article indirectly emphasizes the ethical duty to prioritize the well-being and safety of research participants, minimizing potential harm.
- Article 3 - Prohibition of Torture and Inhuman or Degrading Treatment: This article prohibits torture and inhuman or degrading treatment. In research, it underscores the obligation to ensure that research procedures do not cause physical or mental harm to participants.

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- Article 6 - Right to a Fair Trial: While primarily addressing legal proceedings, this article signifies the importance of fairness. In research, it may be interpreted as a commitment to fair treatment of participants, ensuring equal opportunities and avoiding discrimination.
- Article 14 - Prohibition of Discrimination: This article prohibits discrimination based on various grounds. In research, it reinforces the principle of treating all participants fairly and without discrimination.

3.1.3. European Code of Conduct for Research Integrity

Besides legislation linked to research with humans, the ethical conduct for research needs to be considered. *The European Code of Conduct for Research Integrity* provides guidelines and principles to achieve it. The following points are particularly important in GreenME project:

- Reliability: Ensuring the excellence of research across its design, methodology, analysis, and resource utilization.
- Honesty: Developing, undertaking, reviewing, reporting, and communicating research in a transparent, fair, comprehensive, and unbiased manner.
- Respect: Showing respect to colleagues, research participants, subjects, society, ecosystems, cultural heritage, and the environment.
- Accountability: Taking responsibility for every phase of research, from ideation to publication, including its management and organization. This accountability extends to training, supervision, mentoring, and acknowledging its broader societal impacts.

Currently, this document serves as a reference for ethical management applicable to researchers across all fields involved in projects funded by HEurope. This document also describes several good research practices that can be applied in different contexts and could be important for GreenME related to the research environment, research procedures, safeguards, data practices and management, collaborative working, publication, dissemination, and authorship, and reviewing and assessment.

3.1.4. Research with human subjects in a vulnerable situation

Human subjects are involved in the research carried out by the GreenME project. Moreover, some of the tasks of GreenME require the participation of individuals who can be considered as vulnerable (more specifically, underprivileged) because of their health status (mental health disease), ethnicity, gender, or because they live in underprivileged areas (so potentially have low income and potentially low level of education). The **European textbook on ethics research** has a whole chapter (Chapter 3) considering the ethical issues that can be raised by research involving "vulnerable and non-competent" participants. Vulnerability itself can mean different things. On one side, participants can be considered vulnerable due to their inability to give valid consent due to lack of competence or because of other circumstances. On the other side, vulnerability can also

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be linked to susceptibility to harm or exploitation due to a lack of socioeconomic power or suffering social stigmatization (i.e. underprivileged individuals and populations). Part of GreenME participants will be vulnerable (due to lack of socioeconomic power/experiencing social stigmatization, which makes them underprivileged too) ones. Specific measures may be in place for the protection of the rights of these participants:

- Ensure that the participants are approached with empathy and understanding and try to conduct sensitive recruitment strategies. Involve mental health professionals to address potential challenges and to ensure participants' well-being.
- Conduct check-ins with the participants throughout the project to assess their well-being and to determine the impact of the research on the participants.
- Minimize the physical, psychological, and social risks of the research, and ensure their safety participation.
- Respect diverse cultural norms and values and ensure cultural relevance and community engagement involving community and local representatives.
- Respect participants' choices in relation to their participation, withdrawal, and involvement. Offer decision-making support for those participants that might face challenges in understanding or expressing their preferences because of their mental health status.
- Explain how the information will be handled and protected, assure confidentiality to build trust.
- Ensure that individuals in a vulnerable (in this case, underprivileged) situation can provide genuine informed consent. Ensure that the communication is clear and easy to understand, adapting it to the cultural background of the participants and their context. Provide information in alternative formats to accommodate diverse needs. Participants that are vulnerable because they can not provide consent form by themselves will not be included in the project.

3.2. Main GreenME characteristics relevant for research ethics

In Table 1 we specify the different ethical issues and requirements of each GreenME Work Package (WP).

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WP	Task	Partner responsible	Ethical requirement	Work required for ethical application	Months
WP1	Legal and ethics management	UAB	Ethical treatment of data	Analyse the tasks of the project in which we particularly need to consider ethics and legal requirements. Assist all WPs in the preparation of documentation for ethic commissions (including informed consent forms, information sheets).	M1-M48
WP2	Semi-structured interviews and focus groups to identify the status of green care implementation	SSGW	Ethical approval for conducting the semi-structured interviews and focus groups	Create consent forms and information sheets for this WP2 task. Ensure that all the green care actors that will be interviewed have signed the consent forms. Ensure the privacy of the green care actors interviewed. Obtain the approval of the study by the research ethics committee of the different participating academic partners in each study area.	M2-M12
WP3	Nature-based therapies evaluation	UOC	Ethical approval for each intervention	Obtain the approval of the general and specific protocol for evaluating the intervention by the research ethics committee of the different participating academic partners in each study area. Ensure that the participants have received the information sheet and have fully understood the content. Ensure that all the participants have signed the consent form, that they agreed to voluntarily participate, and they are aware that can quit the project at any step of the process. Ensuring gender-balanced participants and including socially vulnerable (i.e. underprivileged) individuals. Be aware that we will be working with people with poor mental health and that specific ethical principles will need to be considered and followed related to their autonomy and dignity, privacy, confidentiality, decision-making ability, or the fact that they are a group of population especially vulnerable to harm because of stigmatization and discrimination.	M14-M30
WP4 – Task 4.1	Environmental audits	UNIKENT	Ensure that environmental audits are not harmful for the environment.		M12-M18

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WP4 – Task 4.2.	Seld-administered questionnaires	UNIKENT	Ethical approval for the questionnaires self-administrated and recruitment process	Writing comprehensive information sheets and informed consents to be voluntarily signed by the participants. Obtain the approval of the study protocol by the research ethics committee of the country of where each WP4 study area is located. Determine inclusion criteria and the recruitment process to ensure the participation and invitation of individuals from underprivileged areas.	M12-M24
WP4 – Task 4.3.	Development of spatial tools, GIS maps creation	UNIKENT	Ethical approval of the development of GIS maps in each study area – an application for approval will be submitted only if sensitive information will be stored in the maps	Whenever sensitive data is used to develop – and stored in - the GIS maps, writing comprehensive information sheets and informed consents to be voluntarily signed by the participants. Obtain the approval of the study protocol by the research ethics committee from each study area. Ensure privacy and safety of the participants. Explanation of the process that will be followed to select the areas with a high deprivation index in those study regions in which no intervention has been evaluated.	M19-M31
WP4 – Task 4.4.	Development of socio-ecological analyses	UNIKENT	Ethical approval of the socioecological analyses	Writing comprehensive information sheets and informed consents to be voluntarily signed by the participants. Obtain the approval of the study protocol by the research ethics committee from each study area. Ensure that the analyses will be done at the population level, all information will be de-identified, determine which process will be conducted to obtain national and local censuses existing databases and how this data will only be accessed by specific people in each study area.	M32-M38
WP5	Creation of green care community, co-development of national schemes, development of a pilot course to train nature-based therapy providers and development of guidelines	ILS gGmbH	Recruitment of the participants involved in each green care working group	Ensure that diverse actors are involved in the green care working groups in relation to gender and to other characteristics such as education, field of working, level of green care actions…, ensure any information is confidential and that the co-creation process will be public, inclusive, and accessible. Ensure that the guidelines written will maximise benefits for mental health and wellbeing and synergises with nature-based therapy and nature-based health promotion initiatives. Guidelines will be cross-sectorial and aligned with European policies and other plans related to it.	M3-M48
WP6	Communication, dissemination, and exploitation tasks, creation	OC	Audio-visual image, permissions	Ensure the creation of inclusive and accessible materials for the general population. Ensure that names and contact information will be saved in a secure cloud storage site (i.e. Microsoft Teams	M1-M48

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	of transversal and adaptable communication materials			managed by the UAB for the whole consortium to share and save data).	
WP7	Ensure compliance with the ethics requirements	UAB		Follow up GreenME research to ensure it follows research ethics and data protection legality.	M1-M48

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3.3. Ethics self-assessment

1. Human Embryonic Stem Cells and Human Embryos	
Does this activity involve Human Embryonic Stem Cells (hESCs)?	NO
Does this activity involve the use of human embryos?	NO
2. Humans	
Does this activity involve human participants?	YES
-Are they volunteers for non medical studies (e.g. social or human sciences research)?	YES
-Are they healthy volunteers for medical studies?	NO
-Are they patients for medical studies?	YES
-Are they potentially vulnerable individuals or groups?	YES
-Are they children/minors?	NO
-Are they other persons unable to give informed consent?	NO
Does this activity involve interventions (physical also including imaging technology, behavioural treatments, etc.) on the study participants?	YES
-Does it involve invasive techniques?	NO
-Does it involve collection of biological samples?	NO
Does this activity involve conducting a clinical study as defined by the Clinical Trial Regulation (EU 536/2014)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)	NO
3. Human Cells / Tissues (not covered by section 1)	
Does this activity involve the use of human cells or tissues?	NO
4. Animals	
Does this activity involve animals?	NO
5. Non-EU Countries	
Will some of the activities be carried out in non-EU countries?	YES
-Specify: Some activities will be carried out in the US and UK	
In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues?	YES

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-*Specify:* The activities in these countries will be the same as in the EU countries. Thus, we will follow the same data protection and ethics procedures. All activities will be reviewed and approved by the research ethics committees at partner academic institutions in each country to ensure that procedures meet the local and international standards for ethics and data protection and by the UAB (the consortium leader) research ethics committee.	
Is it planned to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna, or flora samples, etc.)?	NO
Is it planned to import any material (other than data) from non-EU countries into the EU or from a non-EU country to another non-EU country? For data imports, see section 4.	NO
Is it planned to export any material (other than data) from the EU to non-EU countries? For data exports, see section 4.	NO
Does this activity involve low and/or lower middle-income countries, (if yes, detail the benefit-sharing actions planned in the self-assessment)	NO
Could the situation in the country put the individuals taking part in the activity at risk?	NO
7. Environment, Health and Safety	
Does this activity involve the use of substances or processes that may cause harm to the environment, to animals or plants. (during the implementation of the activity or further to the use of the results, as a possible impact)?	NO
Does this activity deal with endangered fauna and/or flora / protected areas?	NO
Does this activity involve the use of substances or processes that may cause harm to humans, including those performing the activity. (during the implementation of the activity or further to the use of the results, as a possible impact)?	NO
8. Artificial Intelligence	
Does this activity involve the development, deployment and/or use of Artificial Intelligence? (if yes, detail in the self-assessment whether that could raise ethical concerns related to human rights and values and detail how this will be addressed).	NO
9. Other Ethics Issues	
Are there any other ethics issues that should be taken into consideration?	NO

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3.4. GreenME ethical processes: overall, by WP and by partner

The GreenME coordinating institution (UAB) will be responsible for the ethical considerations, together with the Ethics Advisor. GreenME appointed an Ethics Advisor specialized in research ethics and EU data protection law, Constantin Vica (D7.1). The Ethics Advisor will be consulted on matters related to the recruitment of vulnerable (i.e. underprivileged in the context of GreenME) individuals, and personal data processing. The ethics advisor does not have conflicts of interest and will review the project progress and complete an ethics report to submit during each reporting period.

Prior to data collection, GreenME project as a whole will be reviewed and approved by the Ethics Committee on Animal and Human Experimentation (CEEAH) of the Autonomous University of Barcelona (UAB, https://www.uab.cat/etica-recerca/). UAB

CEEAH was set up by the UAB Governing Board on 25th January 2001 and it is a member of the Network of Ethics Committees in Universities and Public Research Centres in Spain (RCE) from its beginning (https://redcomitesetica.es/).
CEEAH had a key role in the approvement of the "Code of Good Practice in Research". The committee provides guidance to research personnel on adhering to prescribed ethical standards grounded in the principles of beneficence, respect for personal autonomy during research participation consent, and justice. These principles, outlined in influential documents such as the Belmont Report, the Nuremberg Code, and the Helsinki Declaration, have been adopted by various regulations, including Law 14/2007, dated 3 July, on biomedical research and the Spanish law on personal data protection (Organic Law 15/1999). The committee also reviews procedures for each study to ensure the privacy and confidentiality of study participants throughout the data collection, storage, and analysis (in accordance with the Spanish data protection law Organic Law 3/2018 December 5, and the EU digital rights regulation 2016/679 of the European Parliament).

The following principles are the ones that the committee evaluates, and they are followed in GreenME project:

- Benevolence: All efforts will be taken to minimize the potential risks for the study, which are quite low. In addition, to maximize the benefit of the study, all data will be thoroughly analyzed and reports produced to make full use of the data, particularly if important results emerge which could inform improvements in the provision of green care. Protocols, de-identified aggregated data, and reports will be available open access for use by others.
- Justice: This study uniquely includes the perspectives of socially vulnerable (i.e. underprivileged in the GreenME context) groups of people such as racialized immigrant communities, working-class communities, the elderly, and those with disabilities or chronic mental illness. These groups have been particularly chosen as their perspectives and experiences may have been unjustly excluded from past studies on green care, or from accessing green care resources. The purpose of this study is to understand how access to and use of green care can help to

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alleviate mental health inequities by providing more just and fair access to these programs and resources. Therefore, this study intends to purposefully include the perspectives and experiences of these groups.

- Respect for Autonomy: Before participation, informed consent will be collected from all study participants (if participants can not provide informed consent they will be not included in the study). This process will include fully informing potential participants about the risks and benefits of participating in the study, answering any questions the participants may have about the study, and providing written information and contact information. Only after this process will potential participants autonomously decide whether to participate or not and their decision will be respected by study personnel. In addition, participants will have the autonomy to decide not to answer or participate in any part of the study they do not want to participate in and this decision will be respected by the study personnel.
- Privacy and Confidentiality: As described above, all data will be de-identified and stored with encryption and password protection. No study data for individual participants will be published or included in any reports with identifying information. In the case that quotes from interviews are used to illustrate analysis of the qualitative arm of the study, only a general descriptor will be provided so that the quote cannot be linked back to the individual participant.

Once the overall GreenME project ethical approval has been obtained, approval will also be sought from the research ethics committee of the primary academic partner acting as site PI (i.e. where the data will be stored) for each study. Related to it the academic institution committees will review all research involving human subjects at their respective universities with regards to the principals of ethics and justice presented by the Belmont Report, the Nuremberg Code, and the Declaration of Helsinki. Local academic partner review committees will also ensure compliance with the different laws related to biomedical research ethics and personal data protection in each respective study country. The ethics committees meet monthly (or similar, depending on the study country/institution) to review new studies. The committees then request any adjustments or changes to the protocol or study documents.

3.5. Informed consent procedures

Gaining informed consent, rooted in comprehensive information regarding the research's objectives and implications, serves as a tool to engage research participants in the project and is mandatory in all instances. This consent encompasses various aspects, including the use of images, personal data, the transfer of data to third parties (especially those outside the EU), open-access publication of fundamental data post-project completion, and the freedom to withdraw from the project without providing a reason and without facing any consequences. Moreover, consent forms state how data will be collected, protected during the project, and destroyed or reused subsequently, and it states what procedures are going to be followed when unexpected or incidental findings occur.

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In the GreenME project, all individuals involved in any of the WPs that requires their participation will receive a comprehensive information sheet and an informed consent form, both presented in language accessible to participants. These documents outline the research's objectives, methodologies, implications, and potential risks or discomfort. Efforts will be made to ensure participants fully comprehend the implications of their involvement. Furthermore, sheets and consent forms are designed for clear understanding, specific adaptations will be implemented to address unique user needs. Specifically, an oral information sheet and consent form would be administered if better suited for end-user needs. The participation will be entirely voluntary, and participants will be informed of their right to refuse or withdraw without facing any consequences. Steps will be taken to prevent coercion, and alternative communication means will be provided if necessary. Participants' autonomy will be respected throughout the entire process, allowing them to decide whether to respond to questions. During the semi-structured interviews and focus groups development and answering the questionnaires within the evaluation of the intervention, coercion in any form will not be tolerated. Participants will be informed that they can request additional information about the project results if interested.

The informed consent procedure will include fully informing potential participants about the risks and benefits of participating in the study, answering any questions the participants may have about the study, and providing written information and contact information. Only after this process will potential participants autonomously decide whether to participate or not and their decision will be respected by study personnel. In addition, participants will have the autonomy to decide not to answer or participate in any part of the study they do not want to participate in, and this decision will be respected by the study personnel.

Consent forms will be created based on the template for informed consent provided by the CEEAH from the UAB. They will be initially produced and approved in English, and afterwards they will be translated into the local language for each study area: Italian, Swedish, German, Catalan, Spanish and Polish. Other languages will be evaluated, and consent forms and information will be drafted if needed such as Arabic, Urdu, Chinese as in some cases we might be working with ethnic minorities.

Throughout the GreenME project different informed consents will be created for each task that requires it. Three types of participation require specific consent procedures, each with its own consent form, considering variations in data use, anonymization, and pseudonymization levels. For WP2, which includes semi-structured interviews and focus groups of several actors, participants consent to answer different questions and that their answers will be used. For WP3, an informed consent will be required for all those individuals that are participating in the different nature-based therapy interventions, and from which we are going to collect personal data, exposure data, mental health outcomes, and emotional and wellbeing status. Finally, for WP4, a self-administered questionnaire will be circulated, and it will be an online survey, even if it is conducted anonymously, it requires an information note and a request for consent, which is done with a box and a tick. For WP5 and WP6, an information note and a request for consent,

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which is done with a box and a tick. All these consent records must be stored separately and under secure measures. Specifically, informed consents from WP2 and WP3 will be signed in paper, and they will be collected in each study area by the responsible institution and securely stored in a locked room in each of the institutions. As a security measure, signed consent forms are scanned and stored in a secure, encrypted cloud storage with restricted access.

3.6. Potential impact of the project activities

Identifying the potential impact of the project activities to the participants of the projects is essential. In GreenME project as the type and level of participation differs among the WPs different considerations are needed. First, in WP2, there is no expected physical or environmental impact for participants or communities involved in the study. Participants will be given the right to not answer any question if they are not comfortable doing so. Second, in WP3, we anticipate that participants in the nature-based therapy programs will benefit from participation. Risks may include potential physical discomfort- although we have tried to limit programs to those which are accessible to all regardless of level of physical ability and do not require great physical effort; discomfort in answering the questionnaire due to the sensitivity and stigmatization of the topic of mental health and wellbeing- we will ensure that the privacy of all participants is protected and that all participants have the right to skip any questions they are not comfortable answering. Stigmatization of mental health may also vary by country or the culture of individual participants. Data collectors will be trained in cultural sensitivity. Finally, in WP4, there is no expected physical or environmental impact of participation. Audits will not be environmentally harmful.

3.7. Selection and recruitment of participants

Different types of participation are required in GreenME; consequently, different processes of selection and recruitment of participants will be conducted. In WP2, participants of the semi-structured interviews and focus group will be selected based on the map of actors created within the task of identification of stakeholders. In WP3, GreenME project embraces the recruitment of underprivileged individuals (also part of what is considered vulnerable groups more broadly) to evaluate cost-effectiveness of several nature-based interventions in different study areas. Communication with research participants will be achieved through organizations that have experience in working with such social groups and have previously established a trust relationship with the target communities. In our case, nature-based therapy providers and health centre workers such as therapists, psychologists, doctors, or nurses, will have an active role in the recruitment of participants. Finally, in WP4 in each country and case study, contacts with the local authority, and networks and NGOs will be mobilised to reach a sufficiently large sample of the population. Our initial estimate is for 1,000 respondents in each study area, a sample that can be representative for a population of 100,000 and above, but a more precise sample size will be determined after the precise definition of size and population of the case study areas is decided. Social media and online forms

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will be used to circulate questionnaires. Other survey methods can be used depending on each country specific context and supporting partner's particular network amongst which surveys will be conducted.

3.8. Incidental findings

The Bioethics Commission, officially designated as the Presidential Commission for the Study of Bioethical Issues (2009), has issued a report addressing researchers regarding incidental and secondary findings. In accordance with this report, incidental findings can be classified as either "predictable" or "unpredictable."

An anticipatable incidental finding is one that is already recognized to be associated with a specific test or procedure. The defining feature of predictable incidental findings is the acknowledgment that the possibility of encountering them is established, irrespective of their frequency.

Conversely, unanticipatable incidental findings encompass results that could not have been anticipated based on the current state of scientific knowledge. Researchers cannot specifically strategize for these types of findings. Nonetheless, they can actively contemplate how to respond if unforeseen results, particularly those with potential actionable or lifesaving implications, emerge.

Based on the methodology followed in the GreenME project we do not expect anticipatable findings. However, as in WP3 we are going to study different mental health outcomes we need to consider social, behavioural or health unexpected or incidental findings that may require interventions to safeguard the well-being of research participants. Accordingly, during the development of WP3 general ethical committee documentation we will develop a specific protocol to respond to any incidental finding we may encounter in relation to mental health diseases.

4. Data protection procedures

4.1. Research data protection framework and regulations

Data protection is linked to the responsibility GreenME consortium has while managing GreenME participants' information. Apart from the importance of data protection for GreenME participants, data protection also matters to each professional and researcher involved in GreenME, each partner institution and GreenME project as a whole because it directly relates to our professional reputation. Data protection is especially relevant for personal data (such as race, ethnicity, and health; which are collected in GreenME and are considered "sensitive data"; and identifiers such as names or identification numbers). Moreover, it is important to note that data protection is linked to both research ethics and open science.

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The main regulation in the EU in relation to data protection is the General Data Protection Regulation 2016/679 (GDPR). This regulation aims to guarantee that individuals will have guaranteed control over their personal data. Accordingly, the GDPR regulation regulates how organizations must use and process personal data.

Applying GDPR to the GreenME context, the coordinator entity (UAB) must ensure:

- Lawfulness, fairness, and transparency, focusing on that participants data rights are safeguarded and protected.
- Purpose limitation, that is that personal data is used for the specified, explicit, and legitimate purpose it was collected and not further processed in a manner that is incompatible with those purposes.
- Data minimisation, that means that personal data is only processed when necessary (i.e. it is adequate, relevant, and limited)
- Accuracy: taking any step reasonable to ensure that inaccurate personal data is erased or rectified
- Integrity and confidentiality, that is, personal data is processed in a manner that ensures appropriate security, including protection against unauthorised or unlawful processing and against accidental loss, destruction, or damage, using appropriate technical or organisational measures.
- Storage limitation: personal data which permits identification of participants is saved for no longer than is strictly necessary.
- Decisions on a participant will not be based solely on automated processing (including profiling)
- Personal data are not made public by accident.
- Appropriate levels of data security, including pseudonymisation and encryption of personal data
- In the case of a personal data breach, the coordinating entity (UAB) will notify the breach to the competent authority (identified as the European Data Protection Supervisor in 2023) without undue delay and, ideally, no later than 72 hours after becoming aware of it.

However, as stated in the Article 5.2. of the GreenME consortium agreement, "Where necessary, the Parties (i.e. partners) shall cooperate in order to enable one another to fulfil legal obligations arising under applicable data protection laws (the Regulation (EU) 2016/279 of the European Parliament on the protection of people with regard to the processing of personal data and on the free movement of such data and relevant national data protection law applicable to said Party) within the scope of the performance and administration of the GreenME project".

4.2. Main GreenME data characteristics relevant for data protection

GreenME is expected to generate/gather the following types of data:

- Primary data generated over the course of the project, such as:
  - Interview and focus group data (WP2)

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- Semi-experimental data (WP3)
- Survey, audit and spatial data (WP4)
- Policy and practice guidelines (WP5)
- Multimedia documents and audiovisual material (WP6)

- Secondary data from existing sources, such as literature reviews (WP2)
- Administrative data from activities such as :
  - Establishing the green care community, workshops (WP5)
  - Establishing the GreenME European green care network and other dissemination acitivities (WP6).

4.3. Data protection self-assessment

Personal Data	
Does this activity involve processing of personal data?	YES
- Does it involve the processing of special categories of personal data (e.g.: genetic, biometric and health data, sexual lifestyle, ethnicity, political opinion, religious or philosophical beliefs)?	YES
-- Does it involve processing of genetic, biometric or health data?	YES
-Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing (such as, surveillance, geolocation tracking etc.)?	YES
Does this activity involve further processing of previously collected personal data (including use of preexisting data sets or sources, merging existing data sets)?	YES
Is it planned to export personal data from the EU to non-EU countries? Specify the type of personal data and countries involved	YES[1]
Is it planned to import personal data from non-EU countries into the EU or from a non-EU country to another non-EU country? Specify the type of personal data and countries involved	YES
-Specify: Data collected as part of all work packages, including WP3 (evaluation of nature-based therapies) and WP4 (a survey and a socioecological study) which involve the collection of heath and behavioral information will be collected in the UK and the USA (pending external funding) as part of the project. This data will be saved in a secure cloud storage and data management will take place (each WP leader will manage the dataset of their WP and prepare a de-identified dataset that can be used by Consortium members to analyse data)[2]. The data will include: sociodemographic data; self-reported mental health and wellbeing data; behavioral data including	

[1] *This answer has been changed in comparison to the ethics self-assessment sheet that was filled in during the project proposal phase*

[2] This sentence has been changed in comparison to the ethics self-assessment sheet that was filled in during the project proposal phase. During the proposal phase we stated that "This data will be imported to Spain where the project management will take place and these datasets will be analysed together with data from other EU countries."

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access to; use and perception of green and blue spaces; data regarding participation in a nature-based therapy program (time spent in the program, activities, environmental data for the nature-based therapy program)- WP3 only. This data will be deidentified prior to importing it to the EU[3]. The data will be imported using encrypted, password protected file transfer systems.	
Does this activity involve the processing of personal data related to criminal convictions or offences?	NO

4.4. GreenME data and identified specific people

GreenME data will vary in terms of being linked to specific people or not depending on each WP, see Table 2.

Table 2 – Information on how data from each WP will be collected and shared in terms of pseudonymisation, anonymisation and de-identification.

	Collection of participant's data	**Data sharing**
WP2	**Pseudonymisated**: each partner collecting information through interviews and focus groups will keep information linking each identification code with the name of the person interviewed. Contact information linked to names will be kept in a separate file than the rest of data collected.	Data that will be shared with WP2 leaders to build the general GreenME WP2 dataset will be **de-identified** (i.e. identification codes will be included, names will not).
WP3	**Pseudonymisated**: Creation of two databases one with personal information fully encrypted and relating the participant to a code and with restricted access, and another database with de-identified data. As soon as the first descriptive analyses have been performed, the database with personal information will be destroyed and data will be completely anonymised.	Data that will be shared with WP3 leaders to build the general GreenME WP3 dataset will be **de-identified** (i.e. identification codes will be included, names will not). Ensure that personal data will be treated as sensitive data. Ensure safety and privacy of the participants.
WP4	**Pseudonymisated**: In T4.4 we will launch a survey in each partner country, with the same text translated in different languages. When participants fill out the survey in any language and submit it, the responses will come directly to the University of Kents Qualtrics platform. Input data will be then transferred from Qualtrics to a University of Kent SharePoint site. By filling out the survey participants will give information that is sensitive such as approximate residential locations. To reduce the risk of	Once data is collected, we will create anonymised datasets for each country that can be used for national and cross-national analyses. Data that will be shared with WP4 leaders to build the general GreenME WP4 dataset will be **de-identified** (i.e. residential information will not be shared, only information on exposure linked to that residential information). Ensure that in public datasets only aggregated data will be published and specify that data

[3] *To note that the same de-identification process will also be done from non-EU to non-EU countries, and from EU to non-EU countries.*

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	identifying individual participants to the survey, a pseudonymisation process will be undertaken for the survey responses from each country.	will only be accessed by specific researchers in each study area when referring to personal data or sensitive data.
WP5 & WP6	Names and contact information will be collected but will not be linked to any other personal data. Maintain respect and integrity to the different data obtained from the study participants and respect their privacy and safety when sharing it publicly.	

4.5. Data management

The UAB Team, as GreenME coordinator and with the support of the UAB library service, will produce a **Data Management Plan (DMP)**, according to the guidance provided by the EU. The aim of the DMP is to describe the data, generated and/or collected during the project life cycle and how it will be managed. The DMP will also cover which metadata, licenses and documentation will be associated with the datasets; how and when the datasets will be made **openly available** for re-use; the costs and the allocation of resources; and the ethical issues to be addressed (according to what is defined in this document of "Legal and ethics management handbook"). In case parts or versions of the project data cannot be openly shared (e.g. personal data), the DMP will provide proper motivations and data availability statements. The DMP will develop a common protocol for collecting data to guarantee data quality, comparability, and homogeneity. Standards will be used for descriptive metadata and will be applied in the archiving procedure of the data in the chosen repositories and a naming convention will be proposed for exchanging data among the consortium members. Specifically, the DMP will contribute to open science practices by granting:

- Immediate open access to unidentifiable grouped GreenME data through a trusted repository such as Zenodo (at the latest at the time of publication) to ensure access after the lifetime of the project,
- Scientific and technical publications licensed under CC BY-SA (or equivalent) or CC BY-NC-SA (or equivalent) allowed for long-text formats and
- Provision of physical or digital access to data or other resources upon request if used to validate conclusions from scientific publications.

In GreenME, data refers to any kind of **survey data, biophysical measurements, interview and focus groups recordings and transcripts, GIS data, and actor information** used for the implementation of the project and the dissemination of results. To make research data findable, accessible, interoperable and re-usable (FAIR), the DMP will include information on:

(i) which data will be collected, processed and/or generated;
(ii) which methodologies and standards (including confidentiality considerations) will be used in data creation and processing
(iii) the handling (including preservation and access) of research data during and after the end of the project;
(iv) how research data will be shared during and after the end of the project ;
(v) how to make data Open Access;

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(vi) how data will be preserved (including after the end of the project).

UAB will draft a first version of the DMP, which will be delivered within the first six months (D1.2. Data Management Plan, deliverable date: February 2024) and will be in charge of updating it as data sets are produced over the course of the project. The implementation of the DMP, open science and data protection principles will be coordinated and monitored by UAB, by the appointed **project managers (Marta Cayetano/ Susana Aragón)** together with the inputs of partners in charge of the tasks generating, using, or exploiting data and according to AB feedback. We will organize an online workshop with members from the AB to review the DMP and to decide on the detailed implementation of the open science and any remaining issue related with data protection principles.

A revised version of the DMP at GreenME mid-term will be produced (M24) and another revised version by the end of the project (M48). Moreover, as stated in the GreenME consortium agreement, if necessary, the different GreenME partners will sign "a separate data processing, data sharing and/or joint controller agreement before any data processing or data sharing takes place".

In brief, GreenME will provide access to a **secure cloud storage** site for consortium partners only (i.e. Microsoft Teams). The GreenME website will be used as a central catalogue to list available datasets (those available via repositories with their DOI and those available upon request), the list of these datasets will also contain a clear and explicit description on the data and, if possible, the metadata file. Moreover, all GreenME data, outputs and results will be accessible via the Oppla portal (the EU repository for nature-based solutions).

4.6. Data transfer

GreenME consortium includes UK and US as non-EU countries. Accordingly, personal data from WP3 and WP4 (see details in Table 3) will be exported from non-EU countries into the EU, from non-EU to non-EU countries and from EU to non-EU countries.

For the transfer of personal data **from the US and the UK to the European Union** and **from non-EU to non-EU countries**, we will ensure that participants data is protected, and that data transfer has a legal basis. For example, for the data transfer between the UK and the European Unione will be able to transfer data from the UK to the European Union according to the UK International Data Transfer Agreement (IDTA) that came into force on 21st March 2022 (https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/international-data-transfer-agreement-and-guidance/).

For the data that needs to be transferred **from the European Union to non-European Union countries** the European Commission has assessed that US and UK ensure adequate level of personal data protection (comparable to the one ensured in the

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European Union; https://ec.europa.eu/commission/presscorner/detail/eN/ip_23_3721 (US) and https://ec.europa.eu/commission/presscorner/detail/en/ip_21_3183 (UK)). Accordingly, and especially taking into account the Article 45.1 and 45.3 of the GDPR, we will be able to transfer GreenME data from the European Union to US and the UK without having to put in place additional data protection safeguards. More specifically, data transfer from the US will be transferred to the European Union under the EU-US Data Privacy Framework approved by the European Commission in July 2023 (https://commission.europa.eu/document/fa09cbad-dd7d-4684-ae60-be03fcbofddf_en; https://ec.europa.eu/commission/presscorner/detail/en/IP_23_3721). Also, in June 2021, the European Commission adopted decisions to ensure **personal data could flow freely from the EU to the UK** (https://ec.europa.eu/commission/presscorner/detail/en/ip_21_3183). This decision will be re-evaluated in June 2025, so GreenME coordinating entity (UAB) will need to adapt this Management handbook accordingly.

All participants will be informed about the data transfers in the consent forms, according to the Article 13.1.f of the GDPR.

Table 3 – Details of the personal data types and specific transfers in the GreenME project

Type of transfer	From	To	Specific data transfer
From non-EU into the EU countries	US and UK	Spain	• Health data collected during WP3 interventions evaluation in the US and UK will be sent to Spain as the WP3 coordinators to create the WP3 GreenME dataset
	US and UK	Spain, Poland, Sweden, Germany, Italy	• WP3 GreenME dataset (including health data from the US and UK) will be shared with those GreenME countries that are designated to do WP3 data analyses. • Once anonymised by University of Kent, WP4 GreenME dataset (including health data from the US and UK) will be shared with those GreenME countries that are designated to do WP4 data analyses.
From non-EU to non-EU countries	US and UK	US and UK	WP3 GreenME dataset (including health data from the US and UK) will be shared with those GreenME countries that are designated to do WP3 data analyses, including US and UK if they are designated. Once anonymised by University of Kent, WP4 GreenME dataset (including health data from the US and UK) will be shared with those GreenME countries that are designated to do WP4 data analyses, including US if they are designated..

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From EU to non-EU countries	Spain, Poland, Sweden, Germany, Italy	US and UK	• WP3 GreenME dataset (including health data from Spain, Sweden, and Italy) will be shared with those GreenME countries that are designated to do WP3 data analyses, including US and UK if they are designated. • Once anonymised by the University of Kent team,WP4 GreenME dataset (including data from the Spain, Poland, Sweden, Germany, Italy) will be shared with those GreenME countries that are designated to do WP4 data analyses, including US if they are designated.
	Spain, Poland, Sweden, Germany, Italy	UK	• Health data and residence information collected during WP4 (including data from Spain, Poland, Sweden, Germany, Italy) will be sent to UK as the WP4 coordinators to create the WP4 GreenME dataset

Data protection is especially relevant for personal data (such as race, ethnicity, and health; which are collected in GreenME and are considered "sensitive data"; and identifiers such as names).

4.7. Screening and assessment

As detailed in the grant agreement, the appointed Ethics Advisor will submit a report to the European Commission at the end of each reporting period (i.e. at M18, M36 and M48), specifying how the consortium has addressed ethical and data protection issues.

The European Commission can check, review, investigate the proper implementation of the GreenME project and its compliance with the Grant Agreement both during the implementation of the project and afterwards. For this, all signed forms and data will be stored up to five years after the completion of the project locked in UAB given that an audit of the grant can be ordered by the European Commission up to 5 years after the final payment. This includes ethical principles and research integrity.

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