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Twinning for Excellence in Noninvasive Brain Stimulation



# D7.2

## Data management plan

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## Executive summary

The present document is the deliverable D7.2 “Data management plan” of the TWINNIBS project, funded by the European Commission’s under its Horizon EUROPE Framework Programme for Research and Innovation under the grant agreement no.101059369.

The main objective of this deliverable is to address all the requirements and practices for managing the project’s data and documentation throughout the data life cycle.

This document describes the data management of the TWINNIBS project and outlines: what data will be collected, processed and generated throughout the project; how the research data will be handled during and after the end of the project; which methodologies and standards will be applied; whether and how data will be shared and made accessible in open access; how the data will be maintained, preserved and curated, both during and after the end of the project.

This deliverable is considered a dynamic living document that will be regularly updated over the course of the project as the new types of data emerge as a result of the project activities.



## CONTENTS

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1	INTRODUCTION .....	4
1.1	Deliverable scope .....	4
1.2	Reference documents .....	5
1.3	Acronym and abbreviation list .....	6
2	DATA SUMMARY .....	7
3	FAIR DATA .....	9
3.1	Making data findable, including provisions for metadata .....	9
3.2	Making data openly accessible .....	10
3.3	Making data interoperable .....	11
3.4	Increase data re-use (through clarifying licences) .....	11
4	ALLOCATION OF RESOURCES .....	13
5	DATA SECURITY.....	14
6	ETHICAL ASPECTS.....	15
7	OTHER ISSUES .....	16
7.1	ANNEXES .....	17
7.1.1	ANNEX I - Informed Consent form .....	17



## 1 INTRODUCTION

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TWINNIBS aims to strengthen the Institute for Medical Research - IMR's research and innovation (R&I) as well as research management and administration capacities and to develop it into a prospective leading partner in international consortia that can attract strategic investments and R&I funding. TWINNIBS will promote interest in neuroscience research in Serbia and the region, and help to advance it, focusing on the multidisciplinary field of non-invasive brain stimulation (NIBS).

NIBS is a set of techniques for transcranial (non-invasive) modulation of the activity in the specific brain areas and the large-scale brain networks to which they contribute. This is an innovative approach to neuroscience research and, ultimately, the clinical treatment of a wide spectrum of neuropsychiatric conditions. TWINNIBS will be a coordination and support tool for IMR to bring NIBS research in Serbia to a new level by partnering with leading European R&I institutions from Denmark, Italy, Germany, and Austria.

TWINNIBS project includes a comprehensive set of cooperation and coordination activities to strengthen the scientific and technological capacities of IMR, including short term mobility, virtual and in-person short term expert visits, workshops, and boot-camps. A series of collaborative small-scale projects with the personalization of NIBS as an overarching theme are foreseen in the project. In this respect, the majority of research activities will be conducted at IMR - project leading partner from Widening country in line with program objective to raise R&I capacities in Western Balkans.

TWINNIBS is set to strengthen the IMR research management and administration capacities and foster organizational changes through the establishment of The Centre for NIBS as well as R&I Project Management Unit will be established within the IMR. In this respect, the project aims to develop IMR's workflow regarding data management and synchronize it with the data management practices of leading EU partners and Horizon EU requirements and standards.

### 1.1 DELIVERABLE SCOPE

This document provides an overview of data handling in the TWINNIBS project and provides the initial guidelines for the project. Within this document the preliminary information on data that will be gathered and/or generated is described, the standards



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that will be used, the ways the data will be exploited and shared, and how the data will be preserved with details such as ethical, privacy, and security issues. This deliverable shows how the partners involved in this project are going to ensure that research data are findable, accessible, interoperable, and reusable – FAIR. As TWINNIBS is a collaboration and support project with a research component that does not exceed 30% of all project activities, the generation of the research data is foreseen under the WP4 – Towards NIBS personalization (R&I component), and WP3 – Promoting Early-Stage Researchers and capacity building. Under the WP3, the DMP covers the data generated under small scale collaborative research projects (Task 3.2. Bootcamp), as well as ESR’s PhD and MSc projects being realized at IMR. The DMP will be kept up to date over the duration of the project.

Therefore, the DMP will deal with the following questions:

- What is the purpose of the data collection/generation and its relation to the objectives of the project?
- What types and formats of data will the project generate/collect?
- Will the project re-use any existing data and how?
- What is the origin of the data in this project?
- What is the expected size of the data?
- To whom might the data be useful (‘data utility’)?
- How will the FAIR principles be implemented within the project?
- Which resources are dedicated to the FAIR principles’ implementation?
- Which data security measures are set?
- What are the ethical concerns regarding data management?

It is important to note that DMP in its present form is a guiding document established early in the project. As such it cannot cover all possible types of data and outcomes of the research activities. The document will be regularly updated as the project activities progress and will always rely on the provisions set in the Grant agreement and Consortium Agreement.

## 1.2 REFERENCE DOCUMENTS

- TWINNIBS Grant Agreement no. 101059369
- TWINNIBS Consortium Agreement
- Horizon EUROPE Online Manual <https://webgate.ec.europa.eu/funding-tenders-opportunities/display/OM/Grant+management>



- Open Research Europe Data Guidelines [Data Guidelines | Open Research Europe \(europa.eu\)](#)
- Horizon Europe Data Management PlanTemplate <https://enspire.science/wp-content/uploads/2021/09/Horizon-Europe-Data-Management-Plan-Template.pdf>
- Practical Guide to the International Alignment of Research Data Management - Extended Edition. <https://doi.org/10.5281/zenodo.4915862>

### 1.3 ACRONYM AND ABBREVIATION LIST

IMR	Institute for Medical Research, University of Belgrade
R&I	Research and Innovation
NIBS	Noninvasive brain stimulation
ESR	Early-Stage Researchers
DMP	Data Management Plan
TMS	Transcranial magnetic stimulation
tES	Transcranial electrical Stimulation
EEG	Electroencephalogram
FAIR	Findable, Accessible, Interoperable, Re-usable
OSF	Open Science Framework
DOI	Digital Object Identifier
BIDS	Brain Imaging Data Structure
GDPR	General Data Protection Regulation
RIMI	IMR's institutional repository





## 2 DATA SUMMARY

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Under this project, partners will conduct a series of inter-related experiments to tackle the question of how the efficacy could be increased by adjusting NIBS to physical and physiological characteristics of a person, thus bringing novelty and advancements to the field. The project will create new protocols, open tools and methods, data on feasibility and effectiveness of different approaches to reduce the variability in the NIBS effects, as well as provide evidence-based recommendation for future implementation of different NIBS techniques, with the special focus on personalized NIBS.

The purpose of data collection in this project is to better understand the sources of inter-individual variability in NIBS effects, personalise NIBS methods and protocols by optimising stimulation site, dose, type, and timing, thus increasing NIBS effectiveness and the reproducibility of physiological and behavioural outcomes, as well as to translate fundamental research on precision brain stimulation into clinical setting.

The TWINNIBS will generate new data, stimulation protocols, code for assessment tools and data analysis, as well as new knowledge, know-how, intellectual property in the forms of technical and scientific reports, all of which will be open and available to the scientific community and the general public. TWINNIBS project will cover different types of data including: brain stimulation protocol information (e.g. intensity, duration, stimulation site, etc in TMS and tES studies), neurophysiological data (e.g. electroencephalography - EEG), neuroanatomical data (brain magnetic resonance imaging data), cognitive-behavioral data (cognitive tasks), self-report data (questionnaires), rating and clinical data (interviews, clinical, and expert assessment).

To increase the impact of the project and the use of the generated knowledge, open and early access to data, code, research outcomes and publications will be adopted. TWINNIBS consortium is devoted to the principles of transparency, accessibility, and open research process. The research will aim for the highest possible level of transparency, reproducibility and replicability of data and results generated, thus maximizing data utility.

Most of the data will be collected and/or generated during the project (new data). However, some project activities will build upon already existing data (re-use of the existing data), that has been generated by the project researchers in the past, and



which will with respect to intellectual property rights be made available for secondary analysis and re-use. Furthermore, the project activities may extract and systematize publicly available data from research articles published in scientific journals (systematic review and meta-analysis).

As the project progresses the type of data that the project will generate and/or collect will be identified and outlined in subsequent versions of the DMP. Wherever possible the preference will be given to data formats that are standard and open as they facilitate sharing and long-term reuse of data. The expected size of the data is to be evaluated over the course of the project.



## 3 FAIR DATA

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TWINNIBS will manage research data generated during the project responsibly, in line with the FAIR principles for research data (Findable, Accessible, Interoperable and Re-usable), maximizing the effectiveness and reproducibility of the research undertaken.

### 3.1 MAKING DATA FINDABLE, INCLUDING PROVISIONS FOR METADATA

Persistent identifiers will be applied so that datasets can be reliably and efficiently located and referred to, as well cited and re-used. Datasets that will come out of this project will be deposited in a certified trustworthy repository.

All anonymized derived data and metadata files will be stored in the project's publicly available OSF (Open Science Framework) repository as well as institutional or other relevant repositories (e.g., Git-Hub, Zenodo). The OSF repository was the first choice because of its focus on openness and unique identifiers and because it represents an excellent tool for promoting best practices around reproducibility, transparency, and research data management. One of the main features of the OSF is that you can preserve, publish, and share datasets alongside project documentation and generate a Digital Object Identifier (DOI) for each dataset. It is still to be decided which data repository and to what extent except the aforementioned OSF will be used.

Consistent, well-ordered research data is easier to find, which is why the detailed contextual and discovery documentation describing how the dataset was generated and how to interpret and re-use data will be provided by a "readme" file for each dataset. Datasets will be accompanied by detailed descriptions of the procedure employed and variables obtained, as well as all the codes that were used for protocols, assessment tools and data analysis. All materials in repositories will be provided in the English language; if originally implemented in other languages (e.g., behavioural assessment tools and cognitive tasks), both the original and the English translation will be provided. For neurophysiological data the BIDS (Brain Imaging Data Structure) will be followed if applicable. BIDS is a standard for organizing annotating and describing data collected during neuroimaging experiments and is based on the formalized file and directory structure and metadata. Recently, BIDS extensions have been proposed for EEG data and brain stimulation experiments, thus TWINNIBS project will aim to implement these standards into its data management.



Search keywords will be used to enable and maximize data findability, re-use, and exploitation. Keywords will include the name of the project (TWINNIBS) as well as other keywords relatable to the project's topic (e.g., brain stimulation). Dataset specific keywords will be descriptive to the content of the dataset (e.g., EEG, motor control, memory).

It is important to identify and distinguish versions of research data files consistently (version control). The OSF provides built-in version control that records changes to project files and previous versions through OSF Storage. Other version control repositories such as Git-Hub could also be used.

Almost all research domains require specific ways of organizing and structuring research data. Therefore, a well-organized and clear folder structure will be developed and followed. File structure contributes to the clarity of data documentation, and it will be considered thoroughly.

File names, except from uniquely identifying a file and helping in classifying and sorting, provide useful clues to the content and version of a file. File naming will be systematic and consistent across the project. Once established the same file naming strategy will be followed. To achieve consistency and transparency researchers are strongly encouraged to use BIDS (Brain Imaging Data Structure) format for storing and sharing data. More info on BIDS can be found here: <https://bids.neuroimaging.io/> and primer on BIDS use in NIBS can be found here: [https://gin.g-node.org/CIMeC/TMS-EEG\\_brain\\_connectivity\\_BIDS/src/master](https://gin.g-node.org/CIMeC/TMS-EEG_brain_connectivity_BIDS/src/master)

## **3.2 MAKING DATA OPENLY ACCESSIBLE**

Providing access to data is one of the pillars of sound, reproducible scientific research. The underlying principle that will be followed is: "as open as possible, as closed as necessary". The data for which full anonymization in line with personal data protection is possible, will be made accessible by deposition in the certified OSF repository.

The OSF repository does not rely on a proprietary or commercial communication protocol, instead the protocol is open, free and universally implementable. Importantly, it allows for implementation of the embargo period which gives primary rights of publishing and exploitation of the results to its creators and can be implemented in way that protect intellectual property rights. The ownership, dissemination and access rights are specified in the TWINNIBS Consortium agreement.



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Indication whether potential users need specific methods, tools or software for accessing data will be addressed for each type of data. Due to the variety of the data in TWINNIBS project, each dataset will include a readme .txt file outlining specific software requirements for accessing the data. Whenever possible the data will be accompanied by open-source code and accessible using free and open software.

All the matters of rights to control access to data will be discussed by the project partners and will be covered in the next version of DMP.

### **3.3 MAKING DATA INTEROPERABLE**

The data should be able to be combined and used with other data or tools. The format of the data should be open and interpretable for various tools, including other data records. The concept of interoperability applies both at the data and metadata level.

The machine-readable data and metadata will be provided in accessible language by using a well-established formalism in order to maximize interoperability.

The datasets will be accompanied by detailed descriptions of the procedure employed and variables obtained, as well as all the codes that were used for protocols, assessment tools and data analysis. All materials in repositories will be provided in the English language; if originally implemented in other languages (e.g., behavioural assessment tools and cognitive tasks), both the original and the English translation will be provided. To further promote usage of the available resources, all TWINNIBS publications will include links to their corresponding OSF repository.

Data will be fully interoperable - following "as open as possible, as closed as necessary" principle. Access will be provided to datasets that are stored in data files of standard data formats, compliant with almost all available software applications. If there are specific ontologies or vocabularies that will be used for creation of metadata they will be documented.

### **3.4 INCREASE DATA RE-USE (THROUGH CLARIFYING LICENCES)**

Each dataset generated in the project will be accompanied by a data license that details the permissions associated with the use of that dataset. The most used licences for scientific content are Creative Commons licences. The exact licences that are going



to be used in this project will be clearly specified and documented in the subsequent version of DMP, individually for each of the project results and outputs.

According to the type of license, agreements and protocols adopted by the publisher/data source, in the case of collected data, there might be restrictions on data sharing. Each dataset made available in open repositories will provide the specific license of the data both in the readme and in the meta-data JSON file.

Metadata of deposited data will be open under a Creative Common Public Domain Dedication (CC 0) or equivalent (to the extent legitimate interests or constraints are safeguarded), in line with the FAIR principles (in particular machine-actionable) and provide information about the following: datasets (description, date of deposit, author(s), venue, and embargo); Horizon Europe funding; grant project name, acronym, and number; licensing terms; persistent identifiers for the dataset, the authors involved in the action, and, if possible, for their organisations and the grant. Where applicable, the metadata will include persistent identifiers for related publications and other research outputs.

Depending on the concrete output researchers, project partners and publishers may attribute different licence to the data and results such as: the CC-BY license, the CC-BY-SA license, the CC-BY-ND license, the CC-BY-NC license, the CC-BY-NC-SA license, and the CC-BY-NC-ND license as the most restrictive of the six CC licenses.



## 4 ALLOCATION OF RESOURCES

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Creating, managing, and sharing research data carries a cost, requiring the allocation of staff time and other resources. In TWINNINBS project resources for implementing FAIR principles are allocated to the WP7 Communication Dissemination and Exploitation (Task 7.2 Increasing the visibility of research outputs and open science approach). The Open Science Committee, comprising of delegates from all project partners are responsible for setting the rules, making decisions, monitoring the implementation, and mitigating risks in all aspects related to the implementation of the FAIR principles. In addition, the staff-cost within WP3 and WP4 covers activities necessary for the implementation of FAIR principles in the research activities throughout the lifetime of the project. The team member responsible for data management will be specified for each data set individually.

Making material code and data open and available will not impose additional costs to the project, as all repositories and foreseen sharing platforms are free for contributors and users. Any costs related to open access to research data and publications are eligible during the duration of the project under the conditions defined in the TWINNIBS Grant agreement.



## 5 DATA SECURITY

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Storing and ensuring data security and integrity during research requires specific measures. Data should be easy to reach, but at the same time safe and robust. Data should be protected from unauthorized access, changes, or loss.

The basic concept of the 3-2-1 backup strategy will be followed as it eliminates some of the risks involved in backup procedures. That would mean having at least three backup copies of the data, on at least two local (on-site) but different media (devices, storage media), and at least one copy stored in an off-site location ensuring that natural or geographical disasters cannot affect all data copies. Also, a regular schedule for duplicating the data (backup) will be adopted.

Depositing the data generated and scientific outputs of the project on Open Science Framework repository or other trustworthy certified repository allows for long-term preservation and curation, in compliance with EU guidelines. OSF repository is maintained by Center of Open Science, an initiative whose goal is to increase openness, integrity, and reproducibility of research. The OSF repository supports controlled access, so project members can be assigned different permissions: read only, read and write, and administrator. The administrator(s) can determine which parts of the project will be public or private, or which components of a public project can be made private.

All necessary actions will be taken within the project management and by all beneficiaries to ensure compliance with applicable European and national regulations and professional codes of conduct relating to personal data protection. The beneficiaries will implement technical and organizational measures to ensure privacy and data protection rights in the project.

The collected personal data will be stored at the TWINNIBS online collaborative platform based on Microsoft SharePoint, which is a web-based collaborative platform primarily used as a document management and storage system. This tool is provided, administrated, hosted, and maintained by the IT department of IMR in compliance of GDPR regulations.

More detailed information on how the data will be stored and backed-up properly as well as how the security of and access to data will be managed is going to be described in more detail in the updated version of the DMP.





## 6 ETHICAL ASPECTS

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The Ethical aspects of the TWINNIBS project are described in Grant Agreement Annex 1 Part B page 19-20. To ensure adequate implementation and adherence to research ethics, the project has a dedicated WP8 - Ethics requirements. In addition, the project has appointed independent ethics advisor to oversee the project activities. Finally, the TWINNIBS project has a scheduled ethics advisory report and review in middle of the project (month 15) as well as at the end of the project (month 36).

As outlined in the project description the work with patients will be conducted only on voluntary basis with informed consent and maintaining the anonymity of the patients. The confidentiality of personal data and experimental results will be strictly maintained according to European regulations. Unexpected and incidental findings will be addressed by the informed consent procedure and the right of an individual of taking option of knowing/not knowing will be assured.

All research activities involving Human Subjects will be carried out in compliance and with the approval of all involved ethics committees. This will also include the approval of the information sheets and informed consent forms that will be given to the participants in the experiments. No research activities will start before approval is issued and notified by the relevant Ethics Committee. The project will adhere to the WMA Declaration of Helsinki - Ethical Principles of Medical Research Involving Human Subjects (1964) and more recent versions.

The confidentiality of personal data and experimental results will be strictly maintained according to European regulations. The quality and integrity of research outcome material will be maintained in agreement with the good research practice and research ethics codes.

All human participants' data collected over the course of this project will be handled with utmost delicacy. Before data collection takes place, every participant will be assigned a persistent identifier that will be used for labelling and storing data. Data will be completely anonymised before being stored or shared in a publicly available repository. Sensitive data will not be made publicly available in the repository and could only be provided to a licensed researcher upon reasonable request. All data collected within this project are to be carefully protected in compliance with relevant national data protection legislation of the EU member states implementing the General Data Protection Regulation (GDPR).



## 7 OTHER ISSUES

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In addition to the provisions outlined in this document, the project will use of Partner's institutional procedures for data management, such as internal data protection policies and regulations. These procedures are not in the conflict with project's DMP but might impose additional steps to ensure data protection and compliance with national regulation.

For dissemination of the project results partners will make use of the institutional resources, such as institutional repositories (e.g., IMR's institutional repository [RIMI \(bg.ac.rs\)](http://RIMI.bg.ac.rs)), or EU resources for sharing research results and data (e.g. European Open Science Cloud or other resources outlined in the D7.1 Communication Dissemination and Exploitation strategy).



## 7.1 ANNEXES

### ANNEX I - Informed Consent form

#### ***TWINNIBS: "Twinning for excellence in non-invasive brain stimulation in Western Balkans"***

This Informed Consent Form has two parts:

- Information Sheet
- Certificate of Consent

You will be given a copy of the full Informed Consent Form.

- [Information Sheet](#)

#### **Purpose**

TWINNIBS aims to strengthen the Institute for Medical Research - IMR's research and innovation (R&I) as well as research management and administration capacities and to develop it into a prospective leading partner in international consortia that can attract strategic investments and R&I funding. TWINNIBS will promote interest in neuroscience research in Serbia and the region, and help to advance it, focusing on the multidisciplinary field of non-invasive brain stimulation (NIBS). NIBS is a set of techniques for transcranial (non-invasive) modulation of the activity in the specific brain areas and the large-scale brain networks to which they contribute. This is an innovative approach to neuroscience research and, ultimately, clinical treatment of a wide spectrum of neuropsychiatric conditions. TWINNIBS will be a coordination and support tool for IMR to bring NIBS research in Serbia to a new level by partnering with leading European R&I institutions from Denmark, Italy, Germany, and Austria. TWINNIBS will include a comprehensive set of cooperation and coordination activities to strengthen the scientific and technological capacities of IMR, including short term mobility, virtual and in-person short term expert visits, workshops, and boot-camps. A series of collaborative small-scale projects will be conducted with the personalisation of NIBS as an overarching theme. TWINNIBS will strengthen the IMR research management and administration capacities and foster organizational changes. The Centre for NIBS



as well as R&I Project Management Unit will be established within the IMR. TWINNIBS will have a substantial scientific, economic/technological, and societal impact towards outcomes specified in this topic as well as a long-term impact on the R&I in the European space, with a special focus on the Western Balkans region. To realise the full potential of the TWINNIBS project a comprehensive set of communication, dissemination, and exploitation measures will be implemented. Further information: <https://cordis.europa.eu/project/id/101059369>

### **Type of intervention**

Name of the Event

This EVENT will be guided by *Name team member* and documented by *Name team member*.

Personal information about you will not be shared on the platform unless explicitly agreed in advance.

The workshop will be hosted online, the *Date and time*.

### **Voluntary Participation**

Your participation is completely voluntarily, and you can stop your participation at any time.

### **Confidentiality**

We will not share any information about you outside of the project team. The information that we collect from this project will be kept confidential. Information about you that will be collected from the TWINNIBS team will be put away and no-one but the TWINNIBS team will be able to see it. Any information about you will be stored anonymously.

### **Sharing of Research Findings**

We will be sharing what we have learnt with the participants, the TWINNIBS project partners and with a wider public. We will do this by providing written reports. Nothing that you will tell us will be shared with anybody outside the research team, and nothing will be attributed to you by name. We might also publish the results in academic outlets in order that other interested people may learn from our project. Data will only be included in these publications in aggregated and anonymized form.



Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction.

I hereby give consent for my data to be conveyed and documented for the purpose stated above. I confirm that I have been informed of the nature of TWINNIBS and that my participation is voluntary. I am aware that I may withdraw my consent at any time.

I, the undersigned, confirm that (please tick box as appropriate - *to be adapted according to the EVENT*):

I have read and understood the information about the project, as provided in the Information Sheet.	<input type="checkbox"/>
I have been given the opportunity to ask questions about the project and my participation.	<input type="checkbox"/>
I voluntarily agree to participate in the project.	<input type="checkbox"/>
I understand I can withdraw at any time without giving reasons and that I will not be penalized for withdrawing nor will I be questioned on why I have withdrawn.	<input type="checkbox"/>
The procedures regarding confidentiality have been clearly explained (e.g. use of names, pseudonyms, anonymization of data, etc.) to me.	<input type="checkbox"/>
Separate terms of consent for interviews, audio, video or other forms of data collection have been explained and provided to me.	<input type="checkbox"/>
The use of the data in research, publications, sharing and archiving has been explained to me.	<input type="checkbox"/>
I understand that other researchers will have access to this data only if they agree to preserve the confidentiality of the data and if they agree to the terms I have specified in this form.	<input type="checkbox"/>
I, along with the project team member, agree to sign and date this informed consent form	<input type="checkbox"/>



### **Audio and video recordings**

I hereby consent that audio and video recordings will be taken of during the event on *Date*. These recordings and images thereof will be used for marketing purposes, e.g. for publication in print media, online, or on social media. The photographs will be stored securely. If you would like to see your images or would like us to delete them, please contact INSERT CONTACT PERSON (email: INSERT EMAIL).

A copy of this Informed Consent Form has been provided to the participant.

Name participant

Name project team member

Signature participant

Signature project team member taking the consent

Date

Date