# Declaration of truthfulness and accountability

**I declare that I have described the study protocol truthfully. I take responsibility for compliance with the procedures outlined in this form. I have read and taken note of the UM regulations and applicable codes of conduct. I understand that I shall be held responsible for any breach in the research procedures outlined in this protocol.**

**The ERCIC reserves the right to contact the Faculty Dean in case the protocol involves serious ethical issues or a high risk of harm to participants or others.**

*Only scientists with a Ph.D. degree and appointed at an inner-city faculty are allowed to submit a protocol as principal investigator. This requires the use of the Maastricht University email address. Ph.D. students should seek ethical approval through their promotor or principal investigator of the grant that is funding their research.*

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| **Name and title of the PRINCIPAL INVESTIGATOR**  Click or tap here to enter text. | **Contact email for PRINCIPAL INVESTIGATOR**  Click or tap here to enter text. |
| **Title of study protocol**  Click or tap here to enter text. | **Signature of the PRINCIPAL INVESTIGATOR**  *(add text or insert picture)*  Click or tap here to enter text. |
| **In which faculty is the principal investigator based?**  Faculty of Science and Engineering  Faculty of Law  School of Business and Economics  Faculty of Arts and Social Sciences  Other, namely: Click or tap here to enter text. | **Faculty registry number for study protocol, provided by Data Steward (if applicable)**  Click or tap here to enter text. |
| **In which department is the principal investigator based?** *Please do not use abbreviations.*  Click or tap here to enter text. | **Any other applicable registration numbers (grant provider, previous ethics application, etc)**  Click or tap here to enter text. |
| **Ethical approval history (*if applicable*)**  The project has been reviewed by another research ethics committee, namely Click or tap here to enter text.  *In case of research with medical aspects*: The METC has provided a letter to affirm the project is non-WMO applicable  The project has undergone ethical self-assessment as part of the grant application  Other, namely: Click or tap here to enter text.  *If you have answered ‘yes’ to any of the questions above, please attach the corresponding letter of opinion from the respective ethics committee within your application submission (whether or not it was approved). Please ensure to tick the corresponding check-box in question 11.* | |

# SECTION 1: GENERAL INFORMATION

1. **Who will conduct this research? In addition to the PI indicated above, please list any EXECUTIVE researchers and what research activities they will be involved in carrying out. These may include activities such as recruitment, data collection, transcription, analysis, etc.**

*Please include all* ***names, occupations,*** *and proposed* ***roles*** *of researchers in the research project. If individuals for a specific* ***role*** *need to be recruited, you can indicate the anticipated timing for recruitment. Please also indicate the role(s) the PI will fulfil themselves.*

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| **Name** *(if known)* | **Occupation** *(e.g. student, PhD, Post-doc, institutional contact …)* | **Role(s)** |
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1. **Are any grant providers involved in** **the study?**

No

Yes, please provide the name of the organization(s) in full: Click or tap here to enter text.

1. **Which organisation(s) will be involved in the study?***Please list out all relevant institutions, companies, and/or stakeholder groups that will be involved in the research. Please include any organizations involved in recruiting participants, collecting or processing data, or who may have access to non-public aspects of the study (e.g. Prolific, Qualtrics, transcription provider, etc).*

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| **Organization** | **Location** | **Role or activity** |
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1. **Please declare any potential conflicts of interest involved in the study protocol.**Potential conflicts of interest may include but are not limited to the following examples:

* *Do any researchers involved have any individual conflicts of interests, such as an affiliation (past, present, or planned future affiliation) with an institution that has an interest in the proposed study?*
* *Are there any commercial or political interests at stake within or between the listed institutions?*
* *Are there any tensions with ensuring privacy of participants and the intention to inform researchers and the public about the research as part of Open Science?*

Click or tap here to enter text.

1. **In which countries will the study take place?***Please ensure that this answer here covers* ***all*** *activities of Executive Researchers and of any institutions or contract research organizations involved in the research. This may be consequential for GDPR compliance; you are recommended to contact your faculty information officer if you have questions.*

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| **Researcher or organization** | **Research activity** | **Location** |
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1. **Please provide an expected start and end date (if known) for the project for which you seek ethical approval. If it the project includes data or materials from previously conducted research or pilot work, please detail what will be used, and when and where it has taken place.**

Click or tap here to enter text.

1. **What documents are enclosed in the application?**

*Not all documents may be relevant for every project. Please consult your faculty Data Steward and/or Information Officer if you have questions (see further advice in the next section on GDPR). Accompanying documents directed to participants should be submitted in English and/or Dutch and, where necessary, in the language(s) relevant to the research.*

Advertisement(s) of the study

Statement(s) of consent from external organizations where the study takes place

Information letter(s) for research participants (data subjects)

Statement(s) of consent for research participants

Debriefing form for research participants

Protocol(s) for interviews or others carrying out the research

Data Management Plan (DMP)

GDPR registry form

Data protection impact assessment (DPIA)

Any agreements with external organizations, or preliminary documents thereof

Research Ethics Committee opinion letter(s); namely: Click or tap here to enter text.

Other documents, namely: Click or tap here to enter text.

## GDPR/AVG Preparation

This part of the application is meant to prompt researchers to be aware of some definitions and conditions of GDPR/AVG compliance related to academic research. It is not an exhaustive review, but may indicate that further review is necessary.

**You are recommended to consult with your Faculty Data Steward and/or Information Manager on a data management plan and GDPR compliance before completing this form.**

The advice and questions below can help you get started with this process.

The Principal Investigator is responsible for ensuring that your project complies with UM’s Data Management Code of Conduct. If your research involves personal data, it must also be reviewed for compliance with the GDPR, as implemented in the Dutch AVG. If you are unfamiliar with the conditions that may apply to your research regarding data management and GDPR compliance, we recommend reviewing the Maastricht University Research Data Management Code of Conduct available on the University Library RDM Portal.

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| * ‘Personal data’ means any information relating to an identified or identifiable natural person (‘data subject’). An *identifiable natural person* is one who can be identified, *directly or indirectly*, by reference to an identifier such as a name, an identification number, location data, or an online identifier; or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural persons.   *This means that identification is not only limited to direct means (e.g. name, ID number) but also indirect means, such as a combination of points linked to a single observation.*   * ‘Data processing’ means any activity that is performed and executed on the data in question. This includes the *collection, storage, transformation, analysis, communication, and even deletion of the data*. In some cases, the *generation of metadata about the data* may also be considered a form of data processing.   The processing of personal data may occur in activities beyond the research activities, such as   * Recruitment (e.g. activities organized to solicit study participants; may include contact details etc.) * Compensation or reimbursements (e.g. provision of incentives for participation in research; may include contact and financial details etc.) * Communications about the research (e.g. such as scheduling appointments or communicating findings etc.) |

1. **Personal data self assessment: can individual persons be identifiable in your data in any of the following ways?**

your data contains directly identifiable information (for example: name, image, video recording, audio recording, patient number, IP address, email address, phone number, location data, social media data)

it is possible to single out an individual (for example when there are unique data points or unique behavioural patterns which can only apply to one person)

it is possible to infer information about an individual based on information in your dataset (for example, guessing that someone lives in a certain neighbourhood based on where they go to school)

it is possible to link records relating to an individual (for example by combining multiple variables in a dataset or combining with another dataset, via direct or indirect identifiers)

de-identification is still reversible (for example, if a pseudonymisation key still exists for pseudonymised data; see Question 15 for a definition of anonymization vs pseudonymisation)

*These prompts are adapted from the Utrecht University Data Privacy Handbook (*[*https://utrechtuniversity.github.io/dataprivacyhandbook/personal-data-assess.html*](https://utrechtuniversity.github.io/dataprivacyhandbook/personal-data-assess.html)*). If any of these are checked, please ensure that you include a (draft) Data Management Plan and/or GDPR Registry form with this application. Consult your Data Steward to produce this.*

1. **GDPR Special categories: Please indicate if you plan to process data that may reveal any of the following types of categories of personal data.**

*Please check the boxes where applicable*

Racial or ethnic origin

Political opinions

Religious or philosophical beliefs

Trade union membership

Genetic data

Biometric data for the purpose of uniquely identifying a natural person

Data concerning health

Data concerning a natural person’s sex life or sexual orientation

Data concerning criminal convictions or offenses

Other data that may be considered sensitive (e.g. BSN number, financial data, etc.); namely: Click or tap here to enter text.

*If any of these are checked, please ensure that you include a (draft) Data Management Plan and/or GDPR registration with this application. Consult your Data Steward to produce this.*

# SECTION 2: Ethically Sensitive Aspects of the Study

1. **Please describe the study. Include concise information on the background, research questions/aims, research design and methods. Also please explain why this study should take place (i.e., its societal or scientific relevance). Please describe everything in layman’s terms, and do not exceed the word limit.**

**Word count:** Click or tap here to enter text. **(max. 500 words)**

Click or tap here to enter text.

## ***Process of recruitment and initial consent***

1. **Please describe the main characteristics of the research participants and recruitment process:**

* *Individual characteristics: what describes your participants?*
* *Inclusion and exclusion criteria: what makes someone eligible or ineligible to participate?*
* *An estimate of the size of the population of eligible participants and of the sample you anticipate recruiting: How large or narrow is the field of research? Would participants be known or unknown to each other?*
* *The recruitment process: how will participants be solicited, whether actively or passively? by whom and with what technology or form of contact?*

*If your research uses already existing data, indicate what is known about the participants and recruitment process when it was collected, along with how you are able to have access to the data.*

Click or tap here to enter text.

1. **How will you explain your research and its purposes to the research participants? Please consider who your audience is and how your will ensure they are informed appropriately about their rights relating to any processing of their personal data (e.g. right to access, correct or delete data, etc.).**

*Please provide any relevant documents and check for appropriate use of terminology, especially when referring to groups of individuals who may be in a vulnerable situation.*

Click or tap here to enter text.

1. **How will participants be allowed sufficient time and independence to consider their willingness to participate?**

Click or tap here to enter text.

1. **How will informed consent be obtained and maintained throughout the data gathering process? Please explain why you choose a certain method. How do you guarantee that consent is freely given, especially when participants are in a hierarchical relationship with any stakeholders to the research? How can consent be revoked and what is the latest time to do so?**

Click or tap here to enter text.

1. **How will participants and their data be known to researchers? Will their identities and/or data be pseudonymised or anonymized, and if so at what stage in the research process?**

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| Privacy preserving techniques are methods or approaches employed to safeguard the privacy of individuals personal data during its collection, storage, processing, or dissemination. Two common techniques include anonymization and pseudonymisation.   * *Anonymization* is a process of de-identification which produces data that are "rendered anonymous in such a manner that the data subject is not or no longer identifiable" (rec.26 GDPR). Once anonymized, the data is no longer linked to any specific individual and cannot be used to identify them, either directly or indirectly. * *Pseudonymisation* is a process that involves removing or replacing identifying information within a dataset so that the data are de-identified in such a way that they can no longer be used to identify a data subject without the use of additional information. Pseudonymisation most typically involves replacing direct identifiers (such as names or contact details) with 'pseudonyms' (e.g. codes). The direct identifiers that have been removed are then typically stored alongside their respective codes within a key file that is kept separate from the pseudonymised dataset.   For more information on pseudonymisation and anonymization, we suggest exploring the open-source tool created by Utrecht University: <https://utrechtuniversity.github.io/dataprivacyhandbook/pseudonymisation-anonymisation.html>. |

Click or tap here to enter text.

1. **If you are working through institutions (e.g. healthcare or other service providers), how will you make clear your relative independence of the institution and the fact that your research will not necessarily result in a direct benefit for the participants?**

Click or tap here to enter text.

## Process of participation

1. **Please describe the activities the research participants will be involved in and/or expected to perform.**

*Your answer may address some or all of these elements:*

* *What precisely will they do? Over what period or how many repetitions?*
* *How much time will be required? Is this time part of their professional or personal lives?*
* *Who will be involved in the activities? E.g. will they be in contact with one or more researchers or with other participants?*

Click or tap here to enter text.

1. **How will participants be compensated for participation? Describe what form of compensation (e.g. remuneration, benefit in-kind, etc) and illustrate why it is appropriate in this context or for the scope of participation expected. If compensation is not appropriate, explain why not.**

*In case of different treatment groups, please reflect on how you will provide equivalent benefit for all participants, or why dissimilar benefits are warranted.*

Click or tap here to enter text.

1. **What potential risks, harm, inconveniences or discomforts may participants experience in being involved in the study? Please reflect on why it is necessary to expose participants to these conditions and how the benefits of the study outweigh the potential negative effect on participants. In addition, how do you intend to protect participants against any potential negative consequences of participation?**

Click or tap here to enter text.

1. **Are there safety considerations for the researchers and other support staff (e.g. administrators, interviewers, volunteers, etc.) involved? If yes, what are they and how will you protect them from possible negative consequences?**

Click or tap here to enter text.

1. **Does the study include any participants or groups who may be considered vulnerable? If so, please define which characteristics indicate potential vulnerability, describe the potential vulnerability, and elaborate on the specific measures implemented to ensure their protection and well-being throughout the research process. In your answer, please ensure to reflect on potential hidden vulnerabilities that might be signalled through participating in or results from your research.**

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| A “vulnerable person” refers to an individual or group of individuals who may be at increased risk of harm or exploitation due to their diminished autonomy, reduced decision-making capacity, or susceptibility to coercion and undue influence or other personal characteristics, in combination or in interaction with the research activities. *This may include ‘students’ as a category, depending on the conditions for research.* |

Click or tap here to enter text.

1. **Please reflect on the possibility of the research activities to produce incidental findings, meaning results or data that may go beyond your intended scope for research. In your answer, please elaborate on any potential risks for the research participants and/or other stakeholders involved. Please also indicate what measures you will take to help mitigate any risks.**

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| Examples of incidental findings could include triangulating the occurrence of a negative event among participants, such as a significant illness or failing grades, or of potentially beneficial circumstances, such as an expected inheritance or promotion. |

Click or tap here to enter text.

1. **Does the study involve deception? If yes, please explain the reasons for it.**

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| Deception in research occurs when an investigator provides false information or intentionally misleads participants regarding important aspects of a study or research activity. It may be *active* or *passive:*   * *Actively* providing inaccurate details or leading participants to false conclusions for the purposes of researching participant responses * *Passively* allowing incomplete disclosure of information to participants when pertinent information about a study or research activity is omitted from communications with participants.   It is important to note that while some research methodologies may require the use of deception, its use has significant implications for the understanding and consent of participants. It is thus necessary to plan in suitable safeguards, such as a debriefing procedure after participation. Please be aware that deception is especially unadvisable in studies involving minors.  For more information about the ethics of deception in research and the implications for consent, please refer to the current Netherlands Code of Conduct for Scientific Integrity (publicly available), and current GDPR regulation (in consultation with your Faculty’s Information Officer) |

Click or tap here to enter text.

1. **When active or passive deception is involved, how are they debriefed after their participation in the study?**

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| The debriefing provides participants with a full explanation of the hypothesis being tested, procedures to deceive participants and the reasons why it was necessary to deceive them. The central aim is to provide an opportunity for the informant to discuss the research with the researcher.  In cases where participants are put under stress, debriefing may also be used to communicate restorative resources.  The explanation should be given in plain language, and particular care should be given to persons who may be made vulnerable through the research activity. |

Click or tap here to enter text.

1. **How will participants learn about the results of the research in accessible formats (that is, not through scientific publication), if at all? How will you ensure that institutions, organisations and others outside of academia will also benefit from your research?**

Click or tap here to enter text.

# SECTION 3: Data Management

*If you have produced a Data Management Plan with your faculty Data Steward, the questions below may already be sufficiently answered in that form. You may copy the answers here or indicate that the form is attached.*

1. **Please provide a summary of the ethical aspects of your data management plan.**
2. What types and volumes of data do you collect? If you collect personal data, what types do you collect? Who is responsible for data management? How are data management and privacy addressed in the informed consent process?
3. How will the collected personal data be securely stored? What security measures will you implement? How will the data be processed, and who will have access to it? Who will handle data tasks such as transcription, anonymization/pseudonymisation, or coding? Will any metadata or supporting materials accompany the data?
4. Where will the data be stored after the project ends? How long will the collected data be stored? Will it be irreversibly destroyed at some point?

Click or tap here to enter text.

1. **Do you intend to make your data available through a FAIR repository? If so, when and how will you do so? If not, please explain why not? In your answer, please also indicate if other research outputs (like publications) are planned to be open access.**

Please note that it is considered good practice that researchers make their data FAIR, unless they have good reasons not to do so (e.g. because of privacy reasons or because they cannot guarantee the anonymity of their participants). For more information on FAIR data principles, please see the UM Research Data Management Code of Conduct and consult with your Faculty Data Steward about appropriate application of FAIR for your research.

Click or tap here to enter text.