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**Study Protocol Application**

**Use of this Form**

This form should be used for studies in which human subjects are involved or personal data is handled.

ERCIC wants to stress that the purpose of this protocol is to invite the researcher to reflect and explicate her/his choices about ethical aspects of the research design. The purpose of this protocol is *not* to prescribe certain choices. For example, there may be good reasons to *not* guarantee anonymity, or to *not* register informed consent in written form. In all cases, the choice needs to be argued convincingly.

**Signature of the PRINCIPAL RESEARCHER**

**I declare that I have described the study truthfully. I take responsibility for compliance with the procedures outlined in this form. I have read and taken note of the UM data management code of conduct. Hence, I realize that I shall be held responsible for any breach in the research procedures outlined in this protocol.**

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 **Name of the PRINCIPAL RESEARCHER in capital letters**

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**Title of research proposal**

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

**General Information**

1. **In general terms, what is the subject of the study?**

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1. **Are any grant providers involved in** **the study?**
* No
* Yes, namely:…………………………………………………………………………………………………………………….
1. **What is the name and title (e.g. Dr./Prof.) of the PRINCIPAL researcher?**

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1. **What is the email address of the PRINCIPAL researcher?** The principal researcher is the one overseeing the research activities/leading the research.

………………………………….@maastrichtuniversity.nl

1. **In which faculty is the principal researcher based?**

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1. **In which department or section is the principal researcher based?** Please do not use abbreviations.

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1. **Are there any EXECUTIVE researchers involved in carrying out the research? An executive researcher performs research activities, but is not ultimately responsible for the research (e.g. a Ph.D. student or post-doctoral researcher) If so, please list their name(s) and function(s) here.**

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1. **At which organisation other than UM will the study be carried out?** Please do not use abbreviations.

*Note: this question is only relevant if the research is (partly) conducted outside UM.*

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1. **Does the executive researcher work for or has s/he or will s/he work for an institution or otherwise that has an interest in the undertaking of the proposed study? Does affiliation with this institution affect the research in any way such as the kind of results produced and presented? If so, how?**

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**Description of the Study (please keep to 500 words maximum)**

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: ………………… (max. 500 words)**

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1. **What documents are enclosed in the application? (not all are necessary, depending on the nature of your study). Please note that we prefer the accompanying documents to be in English, but are willing to accept Dutch and German.**
* Advertisement of the study
* Statement of consent of the external organisation where the study takes place
* Information letter for research informants (data subjects)
* Statement of consent form for research informants
* Protocol for interviewers or others carrying out the research
* Debriefing form for research informants (data subjects)
* Other documents, namely: …………………………………………………………………………………………………………………
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**Ethically Sensitive Aspects of the Study**

**Please explain below the method of dealing with ethically sensitive aspects of the planned study:**

***Who and what***

1. **Please describe the main characteristics of research informants:**
	1. **Individual characteristics e.g. sex, age, and other social categories**
	2. **Inclusion and exclusion criteria (what characteristics must research informants have and what characteristics must they not have)**
	3. **The recruitment process (in case of an on-line survey, please describe how you secure the access to the survey for the respondents, (e.g. a unique username/password, or a unique web link)):**

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1. **Please describe what activities you will be conducting with research informants:**

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1. **Are there any potential risks, harm or discomfort entailed for research informants in being involved in the study? If so, please reflect on why it is absolutely necessary to expose informants to these risks and on how the benefits of the study outweigh any potential risks and inconveniences for informants. In addition, do you intend to protect informants against potential negative consequences of participation? If yes, how? If not, why not?**

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1. **What additional measures have you taken in case your research informants are minors or are in a vulnerable position or are less able to understand what is going on?**

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1. **How much time will each informant be asked to participate in the study? Please reflect on why this is a reasonable time commitment.**

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1. **Will informants be remunerated for their participation? If yes, what kind of remuneration, how much and why is this an appropriate amount? If not, why do you feel it is appropriate to not provide remuneration?**

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1. **Are there safety considerations for the researchers involved? If yes, what are they and how will you protect them from possible negative consequences?**

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***Relations between researcher and informants***

1. **How will you explain your research and its purposes to the research informants? How will you ensure informants are informed about their rights relating to their personal data, such as their right to correct or delete data (Please provide accompanying documentation (see section III, point 2 above) and avoid academic jargon).**

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| It is important that informants are informed in a way that they can easily understand. Please consider who your audience is and how to inform them appropriately. Take special care when communicating with lay, minor or vulnerable populations. |

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1. **Does the study involve deception (for example, if your work is ‘undercover’)?**

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| Deception is when informants are not informed beforehand of the true nature of the study and what is expected of them. For research purposes, deception is vital to avoid socially desirable answers and demand characteristics, but it also goes against the principle of active, informed consent. In other words, it is a serious measure that should only be used if sufficiently motivated and surrounded with appropriate safeguards, including adequate debriefing after participation. Deception is not allowed in studies involving minors (< 18 years). |

**If yes, please explain why:**

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1. **Are the informants debriefed after their participation in the study?**

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| In case of deception, there is always a debriefing (in oral and written form) immediately after having participated in the study. The explanation should be given in plain language, with emphasis on the actions of the informants and/or what was asked of them and why. |

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

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1. **How much time are the informants given to decide on participation?**

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| It is important that informants are not rushed into participating in the research and have time to reflect on whether they are willing to contribute to the project. |

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1. **Will you guarantee anonymity or pseudonymity alongside consent or instead of consent? Please explain how you will do this.**

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| Anonymization eliminates personal data so that data subjects can no longer be identified. Anonymized data is excluded from GDPR regulation altogether because anonymized data is no longer “personal data.” Pseudonymization replaces personal identifiers with nonidentifying references or keys so that anyone working with the data is unable to identify the data subject without the key. This type of data may enjoy fewer processing restrictions under the GDPR.Please consult your data steward on this matter, in case you have questions.  |

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1. **Will you communicate the results of the research to the informants, apart from scientific publications? If yes, how will you do this? If not, why not? How will you ensure that institutions, organisations and others outside of academia will also benefit from your research?**

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1. **If you are working through institutions (e.g. healthcare) 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 informant?**

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1. **Are there clashes of interest between different stakeholders concerned by the project? For example, there may be tensions between ensuring privacy of informants and the need to inform researchers and other publics. How will you handle these?**

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***Data management and GDPR/AVG Compliance***

You are 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. Your faculty data steward or information manager can help you with this.

‘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, in particular by reference to an identifier such as a name, an identification number, location data, 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.

ERCIC advises you to create a data management plan, with support from the faculty data steward or the research data management specialists at the UM library.

1. **Please describe your approach to data management and privacy:**
2. **Which type and volume of data do you collect? Do you collect any personal data? Who is responsible for data management? How do you include data management and privacy in the informed consent procedure?**
3. **How will the collected personal data be securely stored? Which security measures will you take? How will it be processed, who will have access to the data, who will process it (e.g. who will transcribe, anonymise/pseudonymize, or code it).Will you anonymise or pseudonymise the data? Who will have access to the data? Will any metadata or other supporting material accompany the data?**
4. **Where will the data be stored after the end of the project? For how long will the collected data be stored? Will it be irreversibly destroyed at some point?**
5. **Do you intend to make your data publicly available? If so, when and how will you do so? If not, why not?**

Please note that it is considered good practice that researchers make their data publicly accessible, unless they have good reasons not to do so (e.g. because of privacy reasons or because they cannot guarantee the anonymity of their informants). If you should choose not to make your data publicly available, please explain why not.

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***Research outside of The Netherlands***

1. **Do the countries outside of The Netherlands where you conduct the research have ethical guidelines or data protection laws to adhere to? How will you ensure that these will be adhered to? Does the grant provider require you to obtain ethical approval in the countries where you will conduct research? In case there are no guidelines or requirements in the countries concerned or from the grant provider, will you still seek advice on your ethical procedures from a local institution?**

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