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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 of the PRINCIPAL researcher?**

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1. **What is the email address of the PRINCIPAL researcher?**

………………………………….@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?**

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1. **Are there any EXECUTIVE researchers involved in carrying out 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, if applicable, will the study be carried out?**

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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 (in layman’s terms). Do not exceed the word limit.**

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1. **What documents are enclosed in the application? (not all are necessary, depending on the nature of your study)**

* 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:**

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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, 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?**

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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? (Please provide accompanying documentation (see section III, point 2 above))**

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

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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 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. A debriefing is also required if the purpose of the study has not been explained beforehand or if the provided information was incomplete. 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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***Data management and research dissemination***

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? 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?**

**You are responsible for ensuring that your project complies with the GDPR (e.g. if you are processing personal data); your faculty information manager can help you with this. 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.**

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1. **Do you intend to make your data publicly available? If so, when and how will you do so? If not, why not?**

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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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1. **Will you communicate the results of the research to the informants? 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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***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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