**Ethics Review of niet-WMO-plichtig research with human participants**

Please complete the following in a free style with a high level of detail. The ethics review process is looking to see that you have identified ethical issues and addressed them satisfactorily; further, that you are thinking about undertaking your research in an ethical manner, and can communicate this to your research participants and other people in society generally.

Please attach as an appendix any additional materials to support the application, particularly any information sheets and informed consent forms where relevant.

Return the completed form to:

fhml-rec@maastrichtuniversity.nl

**Investigator Name:**

**email:**

**Project Title:**

1. **The Study**

1.1 What is the nature of the study? What are the key questions that you are seeking to address?

1.2 What are the methodologies that you will employ in the study?

1.3 How will humans be participants in the study (either directly or indirectly, for example, through the use of their personal data)?

1.4 Does your study re-use data that has already been gathered for another project or purpose? If so, do you have permission to re-use that data, and was there the relevant consent for this re-use in the first study? (Please explain, with reference to, for example, previous ethics committee decisions and informed consent protocols.)

1.5 What sort of people will be involved? (For example, professionals in the course of their profession, members of the general public.)

1.6 On what grounds did you determine the number of participants needed for the study?

1.7 On what grounds did you determine that this is a useful study?

1.8 Is this a ‘one-off’/ ‘stand-alone’ project, or do you foresee that you will want to re-use the data in future (different) research, or to share the data with other researchers for their future research? How have you ensured consent for this from your participants?

1.9 If relevant, what is your publication strategy?

1.10 If the work is not to be undertaken only in The Netherlands, what are the countries involved, and is local Ethics Review required in the country/countries where the research is to be undertaken? How will this be achieved?

**2. Identifying Harms**

2.1 What are the possible harms that participation in your study could bring for the human participants? (These could be, for example, physical, psychological, economic, harms, harms relating to privacy, etc.)

2.2 How will you ensure integrity in the use of other researchers’ data and published work?

2.3 How will you ensure within your team that the highest standards of academic integrity are maintained, and that there are mechanisms to raise and discuss concerns within the team (and to the University Integrity Officer)?

1. **Safeguards**

3.1 How will you inform participants about their participation in your study? (Please also comment on any re-use of data issues.)

3.2 Will individuals be invited to participate in your study through informed consent, or are you appealing to, for example, the public interest in undertaking the work (for example, you might be undertaking a participant observation)?

*Please supply details (and, where appropriate, drafts of any forms) of your informed consent process (i.e. both how you will gain informed consent from your participants and how you will evidence that consent), and the information sheets that you will use.*

3.3 How will you process any personal data in the project?

*You should explain the safeguards in place throughout the processing of the data from gathering the data, analysing the data, storing the data, and destroying the data at the end of the period.*

3.4 Who will have access to the personal data?

In particular, will you use de-identification methods (coding, anonymising, etc.) as a protection? Will you engage in “open data” methods of data sharing for integrity issues? Under what conditions will they have access?

3.5 Will there be any reimbursement, remuneration or reward for participation? If so, what is your reasoning for this and is it proportionate and appropriate?

3.6 Are there any further safeguards that you have put in place?

3.7 In what circumstances and to what extent will your participants have the opportunity to withdraw their participation? How will this be communicated to them?

3.8 Is participation in the study confidential? In particular, will participants be identifiable in any publications or other dissemination of research results? If so, will you have a specific consent for this use of the data? If participants will be unidentifiable, how will you ensure this in your publications?

3.9 How will the data be stored, and for how long will it be stored?

As a default, you should use the UM data archiving facilities and procedures to store your data. If you are not proposing to use this, why not?

**4. Self-evaluation**

**4.1 On the basis of your answers in the above sections, do you see this research as posing a “high” or a “low” risk to participants?**

|  |  |
| --- | --- |
| HIGH ☐ | LOW ☐ |

**4.2 Are there particular reasons for this evaluation?**

**5. Any other ethics observations that you wish to make.**

*Here you might, for example, indicate how you will communicate your ethics strategy to third parties - to the broader society.*