The protocol must contain the following information:

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| --- | --- |
| * + 1. **Original title**
 |  |
| * + 1. **Purpose**
 | 1. The project’s research question, hypothesis and rationale
2. Framing and potential
3. If a previous study is being repeated, state the reason for this
 |
| * + 1. **Funding and integrity**
 | 1. Who is the principal instigator and research responsible?
2. Who has financed the project?
3. Do participating researchers have any other financial or personal connection to the funders or other stakeholders in the project?
 |
| * + 1. **Methodology**
 | 1. Design and analysis method
2. Practical implementation
 |
| * + 1. **Considerations on the number of participants**
 | 1. Number of study participants as well as qualitative considerations and reasons for this number.
 |
| * + 1. **Study participants**
 | 1. Inclusion criteria
2. Exclusion criteria
 |
| * + 1. **Language**

Explanation and argument for the choice of language (Danish or other languages) for participant information, questionnaire, if relevant, and consent form. |  |
| * + 1. **Ethical considerations**

Including all inconveniences such as inconveniences of a mental or social nature.  |  |
| * + 1. **Remuneration and/or other study participant compensation**
 |  |
| * + 1. **Recruitment of study participants and informed consent**
 |  |
| * + 1. **The expected scientific and social benefit of the research and how this relates to the potential inconvenience to study participants or others as well as any societal disadvantages.**
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