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. Brief literature review and bibliography 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. **Statistical considerations** | 1. Power calculation or other statistical consideration justifying the number of study participants |
| * + 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. **Risks and inconveniences**   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.** |  |