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| --- | --- |
| **Project identification** | |
| Project name/-description |  |
| Principal Investigator  (Project Manager) |  |
| Entity or person responsible for research’s representative |  |
| Identification in the continuous record of project activities |  |

### The main items in the research plan

Cf. Regulations on the organization of medical and health research § 8

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| --- | --- | --- |
| **Item/chapter** | **Description** |  |
| Front page | The project title and identification in the continuous record of project activities Entity or person responsible for research’s representative Institute where the project is implemented Principal Investigator’s name and dated signature Collaborating institutions |  |
| Summary | A brief summary of the project |  |
| Table of contents |  |  |
| Introduction | Background and background documentation, a brief summary |  |
| Purpose | The project's purpose and objectives |  |
| Ethics in the research assessment | Special emphasis on the risk benefit ratio for research subjects |  |
| Time frame | Planned start and finalization of the project |  |
| Research material | Description of health information and/ or biological material, and their origin |  |
| Deimitations | Deimitations in standardization of materials and / or subjects that are included in the project |  |
| Data registration/ measurements | Description of parameters to be measured or recorded and the reason why theyare assumed to fulfill the project`s purpose |  |
| Measurment-methods | Description of methods or equipment used to perform the specified measurements |  |
| Basis of statistics | Calculation of project size / scope |  |
| Data registration | Systems, including technical solutions, for registration and quality control of data |  |
| Plan for processing | The plan for statistical analysis and other processing and presentation of results, including any transfer abroad |  |
| Adverse events | Procedure reporting of adverse events |  |
| Information and consent | In projects involving the collection of data from research participants/ informants |  |
| Applications for approval | External applications for approval of test plan |  |
| Management of amendments | Internal and external approvals of amendments to the project plan |  |
| Funding | Sources and possible conditions of interest-/ dependency |  |
| Reporting and publishing | Plan for interim report, final report and publication |  |
| References |  |  |
| Attachments | Forms for registration of data Information and consent, if relevant |  |