|  |
| --- |
| **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

|  |  |  |
| --- | --- | --- |
| **Item/chapter** | **Description** |  |
| Front page | The project title and identification in the continuous record of project activitiesEntity or person responsible for research’s representativeInstitute where the project is implementedPrincipal Investigator’s name and dated signatureCollaborating 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 dataInformation and consent, if relevant |  |