**MAIN ELEMENTS OF TRIAL PROTOCOL**

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| **Element/chapter** | **Description** |  |
| Front page | Project title and identification  Sponsor's representative  Institute where the project is being conducted  Project Manager's name and dated signature  Cooperating institutions |  |
| Summary | Brief summary of the trial |  |
| Table of contents |  |  |
| Introduction | Background and background documentation, brief summary |  |
| Purpose | Project purpose and objective(s) |  |
| Research ethical evaluation | Special emphasis on risk/benefit ratio for trial subjects |  |
| Time frame | Planned start and finish |  |
| Research material | Description of health information and/or biological material, and their sources |  |
| Delimitation | Delimitation for standardisation of material and/or trial subjects included in the project |  |
| Trial design | Description of end-points, subject groups, duration, treatment regimes and, if relevant, "blinding" of treatment. |  |
| Data records/measures | Description of parameters measured or recorded and why these are expected to fulfil the purpose of the project |  |
| Investigational medicinal devices | Information about medicinal device in the trial and requirements regarding labelling, storage and handling |  |
| Measuring methods | Description of methods or equipment used to perform specified measurements |  |
| Statistical basis | Calculation of the size/scope of the project |  |
| Data recording | Systems, including technical systems, for recording and quality control of data |  |
| Processing plan | Plan for statistical analysis and other processing and presentation of results, including sending them to other countries |  |
| Adverse events | Procedure for reporting adverse events |  |
| Information and consent | In projects with collection of data from trial subjects/informants |  |
| Applications for approval | External applications for approval of the trial protocol |  |
| Handling of amendments | Internal and external approvals of amendments to the trial protocol |  |
| Financing | Sources and any interest/dependency relationships |  |
| Insurance | Information about |  |
| Reporting and publication | Plans for partial reporting, final reporting and publication |  |
| References |  |  |
| Appendices | Case report form  Information and consent, if relevant |  |