

Relevant topics in a research protocol

Front page	Person/entity responsible for research ("forskningsansvarlig") (email address) Department where the project is to take place Project manager's name and dated signature Cooperating institutions
Summary	Brief summary of the project
Table of contents	
Introduction	Brief summary of the background and background documentation
Purpose	Purpose and objectives of the project
Assessment of ethical considerations in the research	Emphasis on the benefits and risks for research participants
Time frame	Planned start and end
Research material	Description of health data and/or biological materials, and sources of these
Restrictions	Restrictions for standardization of material to be included in the project
Data records/measurements	Description of parameters that are measured or recorded and reasons for assuming that these will meet the project objectives
Measurement methods	Description of methods or equipment used to perform the specified measurements
Statistical basis	Estimate of the project's size/scope
Recording data	Systems, including technical solutions, for recording and quality control of data
Plan for processing	Plan for statistical analysis and other processing and presentation of results, including any release to countries outside Norway
Adverse events/handling of unexpected findings	Procedure for reporting adverse events and handling unexpected findings
Information and consent	In projects involving the collection of data from human subjects / respondents

Applications for approval	External applications for approval of the research plan
Dealing with changes	Internal and external approval of changes to the research plan
Funding	Sources and any interests or dependencies