SP
Study Protocol

# CACHET Study Protocol Template

## A template for describing and applying for approval for CACHET studies

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# About this template

This protocol template is designed to server three purposes:

1. To help outline a scientifically sound clinical protocol for executing feasibility and clinical studies in Copenhagen Center for Health Technology (CACHET).
2. To serve as a template for submitting a research protocol to a journal for archival purposes.
3. To help obtain Ethical approval for the Danish Ethical Committee.

For these three reasons, this template builds on the World Health Organization (WHO) research protocol[1], the Journal of Medical Internet Research (JMIR) Research Protocol guidelines for research protocol publication[2], which again builds on concept of "Registered Reports"[3], and the guidelines from the Danish Ethical Committee[4].

The LaTeXcomments contains instructions for how to fill in the different sections. Remove this section in your protocol.

[1] http://www.who.int/rpc/research_ethics/format_rp/en/
[2] https://jmir.zendesk.com/hc/en-us/articles/115002860428
[3] https://cos.io/rr/
[4] http://www.nvk.dk/forsker/forskertjeklister

# Preface

# Abstract

**Background:**
**Objective:**
**Methods:**
**Results:**
**Conclusions:**
**Trial Registration:**

# Contents

# List of Figures

CHAPTER 1

# General Information

| | |
|---|---|
| **Title** | |
| **ID No.** | |
| **Date** | |
| **Funding** | |
| **Primary Investigator** | |
| **Secondary Investigator(s)** | |
| **Responsible Organization** | |

CHAPTER 2

# Purpose

2.1 Problem Statement, Hypothesis, and Rationale

2.2 Literature and Prior Work

2.3 Research Objectives and Endpoints

2.4 Expected Outcomes

CHAPTER 3

# Methodology

## 3.1 Type of Study

### 3.1.1 Design, Methods, Control Group, Randomization, Placebo

### 3.1.2 Practical Execution

### 3.1.3 Study Plan and Duration

### 3.1.4 Apparatus

#### 3.1.4.1 Software

#### 3.1.4.2 Hardware

#### 3.1.4.3 Other Materials

### 3.1.5 Deviation from Standard Care

## 3.2 Statistical Considerations

## 3.3 Participants

### 3.3.1 Inclusion Criteria

### 3.3.2 Exclusion Criteria

## 3.4 Recruitment Strategy

### 3.4.1 Compensation

### 3.4.2 Informed Consent

See also Appendix C

## 3.5 Risks, Side Effects, and Safety Precautions

### 3.5.1 Safety Considerations

### 3.5.2 Damage Compensation and Insurance

See also Appendix F.

CHAPTER 4

# Data Collection and Management

CHAPTER 5

# Funding Support

CHAPTER 6

# Ethics

APPENDIX A

# Email Template for Danish Ethical Committee

The Technical University of Denmark (DTU) has made the following template for making a short description of a project. This template is intended for the Danish Ethical Committee (Danish: Videnskabsetisk Komite (VEK)) as an initial enquiry as to whether a study is subject for ethical approval at all. The template has been provided by Philip Cash from DTU Management Engineering. The document should be ca. 2 pages and answer each of the following questions.

## A.1 Project Description

A short project description (max. 1 page) describing:

- Project Name
- Responsible researcher
- Project Outline and Main Objectives

## A.2 Subjects

A short description (max. 1/2 page) describing the impact and benefits for the study subjects / patients:

- Who are the subjects?
- What is the intervention (if any)?
- What will be measured?
- What are the expected benefits of the project?

## A.3 Methods

A short description (max. 1 page) describing the methods:

- How will informed consent be ensured and documented?
- How will the intervention be delivered?
- How will data be collected and managed?
- What are the possible risks and side effects?

APPENDIX B

# Participant Information

APPENDIX C

# Informed Consent Form

APPENDIX D

# Questionnaires

APPENDIX E

# Recruitment Material

APPENDIX F

# Documentation of Insurance

APPENDIX G

# Curriculum Vitae and Authorization of Investigators

APPENDIX H

# Acronyms

**DTU** Technical University of Denmark

**CACHET** Copenhagen Center for Health Technology

**WHO** World Health Organization

**EBM** evidence-based medicine

**RCT** randomized controlled trial

**JMIR** Journal of Medical Internet Research

**HCI** human-computer interaction

**CUMACF** CACHET Unified Methodology for Assessment of Clinical Feasibility


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chnology