

**GATE 1-I Project proposal from Investigator**

**INVESTIGATOR INFORMATION**

Date

Name of Investigator

Department and address

E-mail

Phone

Other point of contact  
(if relevant)

**PROJECT INFORMATION**

Project title

Project aim

Type of project

Protocol status

Project description

(Please provide study protocol or  
protocol summary as attached file  
if possible Otherwise, please  
describe. Max 1500 characters  
incl. spaces.



Primary endpoints

Secondary endpoints

## **SDCC STAF INVOLVED**

PI

Researchers

Staff in the Clinic

## **EXTERNAL COLLABORATION**

If the study involves external collaboration, please fill in below, otherwise continue to subject information

Name

Company

Department and address

**Role of the external partner**

Please describe; e.g. funding body,  
protocol development, multicenter  
study etc.

Publication agreement signed

## **SUBJECT INFORMATION**

Total number of subjects

Number of subjects from  
SDCC

Primary inclusion criteria

Primary exclusion criteria

Power calculation

Please describe the power  
calculation behind the expected  
number of subjects. If not  
performed, please explain why.

Recruitment strategy

Please describe the recruitment  
strategy, incl. expected time frame  
for the recruitment.

## **TIME FRAME**

Total time frame

PPFV

FPLV

LPLV

## **EQUIPMENT NEEDED**

DEXA	If yes, expected number
Eye examinations	If yes, expected number
eGFR	If yes, expected number
Metabolomic analyses	If yes, expected number
Other equipment needed, please describe	

## **REGULATORY REQUIREMENTS**

Medical Agency approval (LMST)	If yes Journal number  If no; submitted  Date, if submitted  Expected submission date, if not submitted
Ethical approval (VEK)	If yes Journal number  If no; submitted  Date, if submitted  Expected submission date, if not submitted
Data Agency approval	If yes Journal number  If no; submitted  Date, if submitted  Expected submission date, if not submitted

Who is data owner and responsible for the application?

Is there a need for data processor and/or sub-data processor agreement?

Is the study registered in a public database?



## **BUDGET**

Funding source

Budget responsible

Detailed budget

Please provide detailed budget.  
Can be an attached file. SCREEN  
has a budget template if  
needed.