Manual for Project Application

Approval of projects to be run on Statistics Denmark servers follows a sequence as followed. Each part is further described below.

1. Define a project with a protocol

2. Define a list of data for that project

3. Obtain approval from the Data Protection Agency (RegionH: Videncenter for Dataanmeldelser)

4. Obtain permission from Statistics Denmark (Danmarks Statistik = DST)

5. Based on the approved permission of DST an application is sent to Danish Health Data Authority (Sundhedsdatastyrelsen =SDS) in order to obtain data directly from them or from our Project Database

6. DST is applied to transfer the data

7. Additional approvals may be necessary from RKKP and similar organisations

**1. Define a project with a protocol**

The key to approval from the organisations we are dealing with is limitation. Projects need to be specifically defined and limited in perspective. There is a formal set of requirements for a protocol to SDS and none to DST – we therefore propose that the SDS requirements are used. The manuals are in Danish, and it is wise and necessary to write the protocol in Danish. The following manual on how the to write the protocol with the required topics can also be found on the SDS homepage (https://sundhedsdatastyrelsen.dk/-/media/sds/filer/forskerservice/krav-til-projektbeskrivelse.pdf?la=da)

1.1 Introduction

A brief introduction to the subject

1.2 Aim

The aims of the project to be described briefly

1.3 Problem formulation

If possible, this should be formulated as distinct questions that the conclusion of the project should answer.

1.4 Data and Methods

How will the project answer the problems formulated? Which data are used? How are the data used?

1.5 Publication of results

How and when are the results published

1.6 Perspective

What knowledge of relevance for society can this project contribute to?

1.7 Ethical considerations

List approvals necessary for the project (e.g. Approval from the Videncenter for Dataanmeldelser, RKKP, Styrelsen for patientsikkerhed,and when relevant an ethical approval)

**2. Define a list of data (Udtræksbeskrivelse)**

Separate lists need to be made from datasets from DST and SDS – and other sources. These lists need to be accompanied with explanations to how they are necessary for the project.

2.1 – Define the population with wording that easily reflects the programming which generates the population. Long explanations are necessary if the entire Danish population is requested.

2.2 – Define the datasets and those variables that are requested from DST.

2.3 – Define the datasets and variables that are requested from SDS.

2.4 – Define the datasets and variables requested from other sources. For these datasets it is necessary to create tables (excel recommended) where each variable requested is provided with a short explanation of why this variable is necessary for the project.

**3. Obtain approval from the Data Protection Agency**

The application is performed by our data manager. The main input needed from each project is:

3.1 Project title

3.2 Short description in Danish

3.3 Number of study objects involved – be careful not to underestimate as the number may change by slight changes in definition of the population

3.4 A list of which dataset/registries are included in the project

**4. Obtain permission from Statistics Denmark**

The application to DST is performed via e-mail and does not require further forms to be completed.

**5. Obtain permission from SDS**

With approved permissions from the Data Protection Agency and DST an application can be made to SDS. This requires a form to be completed. The main information apart from the protocol and data description are:

5.1 Title of project

5.2 Abstract for project in Danish

5.3 The protocol described in point 1. and the “udtræksbeskrivelse” described in point 2.

5.4 List of requested registers

5.5 Approvals from relevant sources.