Roles in research projects

Guidance on data protection in research

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DATATILSYNET

Contents

Introduction

Private companies, public authorities, natural persons, institutions or other bodies contributing to a research project may have different roles under data protection law in research projects. The role of each party in a research project depends on the context, and a party may have different - or no - roles in different contexts.

It is important that each party determines whether they are a data controller or a data processor, as the requirements for data controllers and data processors are different. Basically, it is the data controller who is responsible for ensuring that the processing of personal data complies with the rules of the General Data Protection Regulation. As a data controller, you must, among other things, ensure that you

- is allowed to process the data in the possession of the controller and any data processors (i.e. whether there is a legal basis for processing the data),
- are able to comply with data subjects' rights (e.g. fulfill the duty of disclosure), and
- Ensure that any personal data breaches are reported to the Danish Data Protection Agency within 72 hours.

If you as a data controller entrust personal data to a data processor, you are still responsible for ensuring that the data processor - in the same way as the data controller itself - processes the data responsibly. In this regard, the data controller must

- ensure that a data processing agreement has been entered into with the data processor, including that the data processor is obliged to assist the data controller in complying with the above obligations, and
- carry out an appropriate control (supervision) of the processor.

If the parties contributing to a research project are unsure who is responsible for complying with the various data protection regulations, there is a risk that neither party assumes responsibility, or that one party assumes a responsibility that they do not actually have.

It is therefore very important that the parties - prior to the initiation of the processing of personal data - clarify their role under data protection law in connection with the research project.

The purpose of this guide is to point out a number of elements that you, as a party to a research project, can emphasize (and not emphasize) when assessing your role or the role of others. The guide also contains a number of practical examples that you can use when assessing your own or others' roles.

The Danish Data Protection Agency is aware that roles may change due to changes in the actual circumstances of the project. The actors must therefore periodically reconsider their data protection role in the project and make the necessary agreements.

1. Definition

Within the data protection rules, a distinction is made between the roles of data controller and data processor. In addition, several parties can be joint controllers.

A data controller is the one who decides why the personal data is to be processed (determines the purposes) and how the personal data is to be processed (determines the means). For example, it can be a natural person, a legal person or a public authority.

In this context, it is important to note that it will typically not be the individual researcher or project manager who is the data controller. Rather, it will generally be the organization to which the researcher, project manager or similar is affiliated and in that connection performs a task for. For example, this could be a region[1] , a university or a pharmaceutical company.

If you determine the essential elements of the data processing that takes place as part of the research project, you will be the data controller for the processing of the data. The following questions can help clarify whether you decide on the "essential elements" of the processing and thus point towards you being the data controller.

Decide on the essential elements?

- Do you decide which stakeholders to include in the project?
- Do you decide which personal data to process, including collection?
- Do you decide how long the personal data will be processed, including if and when the data will be deleted?
- Decide who to share personal data with?

If it's not you but someone else who decides these elements, it may suggest that another party is the data controller.

If you do not determine the essential elements but still have a role in the project, this may mean that you are a data processor, depending on the circumstances.

A data processor is a natural or legal person, public authority, etc. who processes personal data on behalf of the data controller. Unlike the data controller, the data processor does not decide why or how personal data is processed.

The data controller may leave the data processor a certain margin of discretion as to how the data controller's interests are best served. This means that the data processor may, among other things, choose the most suitable technical and organizational means for data processing, without the data processor thereby becoming the data controller.

Finally, you may also determine the purpose and means of data processing together with others. If this is the case, you will be joint controllers. However, if you and any other parties process the data for your own purposes, you will each be an independent data controller.

1 In Denmark, the regions are responsible for healthcare. This means, among other things, that hospitals are run under the responsibility of the regions, and that it is therefore the region that will be the data controller for the processing of data that takes place at a hospital

The parties contributing to a research project may thus have the following data protection legal roles:

Data protection law roles

- Data Controller
- Joint data controller (for part or all of the project)
- Data processor

2. Assessment

When assessing whether you and/or others are (joint) data controller(s) and thus have decided why data is processed/collected (determines purpose) and how data is processed (determines means), you can emphasize the following elements as an interpretation contribution.

It is important to be aware that the elements can point in different directions depending on the context. Thus, it will not always be possible to answer "yes" or "no" to all questions. In these cases, you must weigh the elements against each other and assess which construction has the most and most weighty elements.

The assessment of data protection law roles should be on a per activity basis. This means that you may be an independent data controller for one part of the processing, but have joint data responsibility with another actor for another part of the processing.

If you cannot say "yes" to any of the questions below, it may indicate that you are a data processor. This is true even if you make certain decisions related to the research project and its execution, such as which hardware or software to use in the execution of the project.

2.1 Moments of significance

2.1.1 Does the obligation come from law?

You may be required by law to be a data controller or be obliged to process selected types of personal data for specified purposes.

If this is the case, you will be the data controller for the processing that takes place based on the obligation or because it is directly stated in the law. An example of this is the legal obligation for doctors to keep records of patient treatment.

In other cases, the legislation may contain more general provisions stating that you are required to perform an overall task. The legislation will then leave more leeway for how the data is to be processed and will not clearly indicate whether you are a data controller or not.

2.1.2 Are you subject to professional obligations and standards?

The healthcare sector in general - and the *life* science *industry in* particular - is a highly regulated field. The players in this sector are subject to a wide range of legal obligations that place demands on the activities carried out and the professionalism of the employees who perform them.

For example, there are many rules governing when and how clinical trials can be conducted. Similarly, doctors, nurses and other healthcare professionals are subject to professional obligations that they are obliged to act in accordance with. Finally, laboratories, etc. may be subject to professional standards that the actor has undertaken to observe, for example, in order to obtain or maintain a general certification.

In some cases, these legal and professional obligations and professional standards may mean that the actor in question is prevented from following a detailed instruction from a business partner; for example, to process personal data in a specific way. If this is the case, the actor in question will not be able to assume a role as a data processor and process data on behalf of a data controller. In that case, the actor will be an independent data controller for the processing activities that are subject to professional standards that are incompatible with acting on instructions. This applies even if the activity in question is prompted by, for example, a research collaboration.

For example, doctors who test a new surgical method as part of a research project will still be bound by their medical oath and will, if necessary, be obliged to perform the operation in the most responsible manner, possibly without providing the information that is

relevant and necessary according to the protocol. In such cases, the physician will not be able to follow an instruction from the actor who prepared the protocol.

Similarly, a laboratory may be subject to professional standards for the analysis of blood samples, for example. However, such professional standards will most often require the use of specific equipment or the use of a specific procedure. The laboratory will thus to a lesser extent be obliged to act independently. In this case, the laboratory may follow an instruction to analyze a specified number of blood samples or an instruction to test the blood samples for a specific substance, etc. In this case, the laboratory could assume the role of data processor.

2.1.3 Did you initiate the project?

If you are the initiator of a project, this may indicate that you are the data controller. If you are several parties who have initiated the project, this indicates that you are joint controllers.

This is because the party that initiates a project will often (help to) define the framework of the project.

2.1.4 Have you created and approved the research protocol?

If you have prepared or had a significant influence on the preparation and approval of the research protocol, this indicates that you are the data controller.

If the research protocol has been drawn up jointly with others, this generally indicates that the parties who have drawn up the protocol are joint controllers. This is because the protocol will in many cases set the framework for the project by defining the purpose and execution of the processing of personal data in the project.

In such cases, however, you should be aware of what each party's contribution to the protocol has consisted of. If a party only has minor professional input to the preparation of the protocol, which does not influence how data processing takes place, this does not indicate that this party is the (joint) data controller. In case of doubt, you must therefore assess the contribution of the specific parties to the preparation of the protocol.

2.1.5 Are you funding the project?

If you, for example as a research institution, have applied for and obtained funding for a project, for example through a foundation, this indicates that you are the data controller, as you determine how the project is carried out. If the foundation does not have an influence on the implementation of the project, the mere fact that the foundation contributes funding will not have any significance under data protection law.

If you and a number of other research institutions jointly carry out a research project, but only one of the institutions applies for funding for the project, for example from a foundation, this does not change the fact that you are joint data controllers across the research institutions - provided that all the institutions have had a significant influence on the organization of the project.

If, on the other hand, you enter into a collaboration with a pharmaceutical company or other type of sponsor that has wishes and requirements for how the project should be carried out as a condition for the company's (co-)financing of the project, it would suggest that the parties - you and the company - are joint data controllers for the project.

2.2 Moments that don't matter

When assessing whether you and/or others have decided why data is processed/collected (determines purpose) and how data is processed (determines means), and thus are the (joint) controller(s), the following factors are generally not considered significant.

2.2.1 Internal work distribution

If you have determined that you are joint controllers, you must decide together how you will handle and comply with the data protection rules. This division of roles, which you have agreed internally, may mean that you each handle different parts of the processing or process different

volumes of personal data. However, this does not change the fact that both parties are joint data controllers.

2.2.2 Cross-border collaboration

Cross-border collaboration does not affect the division of roles.

However, there may be local legislation in the country where one or more business partners are located, which the party will be obliged to comply with. If this is the case, this party will most likely be the (independent) data controller for this separate processing.

In addition, you should be aware that depending on the location of the business partners, a legal basis may be required for the transfer of personal data to them.

2.2.3 Authorship

The fact that a researcher in a research project has been assigned authorship of a scientific article does not affect the distribution of roles. This is because it is typically the organization as a whole and not the individual researcher who is the data controller.

2.2.4 Appearance

It is not in itself decisive for the division of roles who is in contact with the subjects and thus could appear as the data controller to them.

This could be the case, for example, where a hospital on behalf of a research institution collects information in the form of questionnaires (which are not covered by the doctor's record-keeping obligation) about patients' experiences at Danish hospitals. The fact that the hospital is in contact with the patients does not in itself mean that the hospital is the data controller if the hospital has not contributed to determining the purpose or means of processing patient data.

3. Examples

The following examples are not an exhaustive list of all the different constructions of controllers, processors and joint controllers that may arise in practice. The examples are only interpretative and the assessment of the roles in each example may be different if the assumptions of the example change.

The examples are based on scenarios that stakeholders have shared with the Danish Data Protection Agency.

In the examples about hospitals, these are referred to as data controllers. However, in the case of public hospitals, the region to which the hospital belongs will be the data controller for the processing of personal data.

3.1 Individuals' roles

3.1.1 PhD students

A PhD student is enrolled and employed at a university.

The university is the sole data controller, as the university defines the purpose and means of the processing of personal data carried out by the PhD student as part of his or her PhD project. The PhD student is merely a part of the university. This division of roles is not changed by the fact that the PhD student is given a wide latitude to decide how the processing should take place. This may include, for example, determining what data is collected and processed, what software is used or what equipment is used. Although the PhD student can act with a certain degree of independence, the university will still be considered the data controller, as the PhD project is planned and carried out under the auspices of the student's PhD employment at the university.

3.1.2 Industrial PhD students

An industrial PhD student is partly employed by a company and partly employed and enrolled at a university.

The company and the university have jointly determined the purpose of the PhD program and have therefore essentially planned how the student will carry out the processing of personal data. Therefore, the company and the university are joint data controllers. The PhD student is part of the company as an employee and part of the university as an employee and student and therefore does not have an independent role.

3.1.3 PhD project by region

A PhD student is enrolled at a university and has a main supervisor who is employed at a hospital. The main supervisor, in connection with his/her employment at the hospital, has prepared the project and recruited the student to carry out the project. The university has no influence on the project.

The hospital has determined the purpose of the PhD project and essentially planned how the student will carry out the processing of personal data. The hospital is therefore the data controller. The main supervisor has no independent role under data protection law as he is part of the hospital. The university has no role under data protection law for the processing of personal data in connection with the project.

3.1.4 Funding for a PhD project

A PhD student is employed and enrolled at a university and receives external funding from a foundation for their PhD project.

Regardless of the degree of independence that the student has in carrying out his or her PhD project, the university is the data controller for the processing of personal data that takes place in connection with the project. This is because the project is carried out under the auspices of the PhD student's employment at the university, and the PhD student is thus part of the university. Since the foundation only finances the project and has no influence on the project, including what data is processed and what methods are used, the foundation has no independent role under data protection law. The university is therefore the sole data controller, regardless of the fact that the funding comes from elsewhere.

3.1.5 External supervisor on PhD project I

A PhD student is employed and enrolled at University A. For the purpose of professional sparring, an external supervisor from University B is assigned, but does not receive any personal data. During the project, the external supervisor provides input on how the collected data can be processed, but the student is not obliged to follow this input.

University A is the data controller for the processing, as the PhD student is enrolled at University A. The external supervisor has no independent role under data protection law in relation to the processing of personal data in the PhD project. This is because the external supervisor has no control over why and how personal data is processed as part of the PhD project, as the PhD student is not obliged to follow the external supervisor's input.

3.1.6 External supervisor on PhD project II

A PhD student is employed and enrolled at University A. For the purpose of academic sparring, an external supervisor from University B is assigned. University B contributes a supplementary dataset. During the project, the external supervisor helps decide how the collected data can be processed. University B subsequently wishes to process the personal data for another research project.

Universities A and B are joint data controllers for the processing of personal data in connection with the PhD project. This is because they jointly decide why and how the data will be processed. University B is an independent data controller for its subsequent processing of personal data for another research project.

3.1.7 Research project and Master's thesis I

A researcher at University A hires a master's student as a research assistant who is tasked with collecting and analyzing personal data. As part of their master's thesis, the student is instructed to further analyze the collected data.

Both the collection of data in the research project and the subsequent use in the Master's thesis is done on behalf of the university, which is the sole data controller. Both the researcher and the graduate student are part of the university and therefore have no independent role under data protection law. This is because the university provides specific instructions to the student on the purpose and means of processing.

3.1.8 Research project and Master's thesis II

A law student receives access to documents containing personal data in connection with her master's thesis.

The university is not the data controller for the student's processing of personal data.

3.1.9 Researcher on leave

A researcher employed at a university college works on a research project initiated and otherwise determined by the university college. The researcher is granted unpaid leave from their position in order to take up a research stay at a European university. During the stay, the researcher must continue to work on the specific research project and therefore retains their IT equipment and access to the university college's IT environment. The researcher is instructed to continue to comply with the university college's guidelines for the processing of personal data.

The university college has established the framework for the research project, including instructing the researcher in the use of IT equipment and access to the school's IT environment. Therefore, the school is the data controller for the processing of personal data carried out as part of the research project. The researcher has no independent role under data protection law, as he is part of the university college. The fact that the researcher is on leave and affiliated with a university during this period does not affect this assessment.

3.1.10 Lending a researcher

A company wants to conduct a trial in order to develop a product. The company therefore enters into a research collaboration with a university, which is tasked with conducting tests and collecting the necessary data, including personal data. The university organizes the trial itself. During the trial, the university realizes that it does not have the necessary time resources and competencies to carry out the analyses required by the project. However, the university knows that a researcher employed by the company has experience with the tasks in question and therefore asks the company for the researcher's help. The university and the company then enter into an agreement on the loan of the researcher to the university for the purpose of performing these analyses. In connection with the work performed for the university, the researcher is subject to the university's instructions on which tasks are to be performed and for what purpose.

The researcher is part of the university. This is not changed by the fact that the researcher is also employed by the company, as the work for the company is separate from the assistance to the university. The researcher therefore has no independent role under data protection law. The university is an independent data controller, as it organizes the trial itself and is not subject to the company's instructions in connection with the conduct of the trial. The company has no data protection role in connection with the project itself, as the company does not process personal data. If the company receives a copy of the personal data from the trial after the trial has been completed, the company will be an independent data controller.

3.1.11 Dual employment I

A researcher is employed at both University A and University B. The researcher is working on a research project at University A. The researcher continues working on the project while present at University B, using University B's research infrastructure.

University A is the data controller for the processing of personal data in connection with the research project. As University B does not determine the purpose and means of processing personal data in the research project, University B will not be the data controller. Therefore, the researcher will only be able to use University B's research infrastructure to work on University A's research project if a data processing agreement is entered into between University A and University B.

3.1.12 Dual employment II

A doctor is employed by a hospital and a university. At the hospital, the doctor collects a range of personal data in connection with patient treatment. The doctor wants to research this data for a newly started research project at the university.

The hospital is the data controller for the processing of personal data that takes place in connection with patient treatment and for the transfer to the university. The university is the independent data controller for the processing of personal data in connection with the research project.

3.2 Collaboration between institutions

3.2.1 Collaboration between hospitals

Hospital A has planned and decided to carry out a research project. Hospital A prepares the protocol and defines the content and methods of the project, including which analyses are to be carried out. Hospital B will contribute to the project by recruiting participants from its own hospital, obtaining participant consent, treating its own patients according to the protocol, collecting personal data and disclosing information from its own patient records.

Hospital A is an independent data controller, as Hospital A alone decides the purpose and means of processing personal data in the project. Hospital B is the independent data controller for its own patient records and for the disclosure of information to Hospital A. The doctors conducting the research project will generally be subject to professional and legal obligations. These obligations may mean that the doctors will not be able to follow instructions on the processing of personal data. The hospital will therefore not be able to assume a role as a data processor in connection with the research project. Hospital B is therefore not a data processor for Hospital A.

3.2.2 Internal work distribution

Four university colleges are collaborating on a research project. In connection with the project, interviews and observations will be conducted. The project is anchored in an interdisciplinary collaboration between the university colleges. Researchers from the university colleges have worked together to define the project, how it will be carried out, what questions the participants will be asked and what observations will be recorded. The researchers have also decided that the personal data will be stored in a secure environment at one of the university colleges.

The university colleges are joint data controllers, as they have jointly decided and organized the research project and the data to be included in the study. This also applies even if the parties have decided to store the personal data at one of the university colleges.

3.2.3 Visiting researchers

University A and University B have planned and decided to carry out a research project. The parties have jointly prepared the project description. The universities each contribute information to the project that they have previously collected for their own purposes. In connection with the research project, there is an ongoing mutual exchange of researchers from one university to the other (guest researchers).

The universities have jointly prepared the project description and thus decided on the framework for the project. The universities are therefore joint data controllers, while the researchers do not have independent data responsibility, as the researchers are part of the universities.

The universities are each independently data controllers for the personal data that they have previously collected and that they pass on for use in the new project, where they, together with the other universities, are joint data controllers for the processing of all personal data included in the project.

3.2.4 Researcher collaboration

A researcher from Region A specializing in diabetes and a researcher from Region B specializing in heart disease have planned a joint research project. The study will investigate the connection between diabetes and a large heart. The researcher from Region A has written the part of the protocol that deals with diabetes and the related studies. The researcher from Region B has written the part of the protocol that deals with the large heart and the related studies. Both researchers have read through the final protocol and have jointly decided what to include in the parts of the protocol where their specialties intersect.

This is a joint data responsibility between Region A and Region B. The regions have jointly decided on the organization of the trial and the data to be collected as part of the trial, even if the two researchers have each written the part of the protocol that relates to their respective specialties.

3.2.5 University researcher's later employment

While working at a Danish university, a researcher, along with other university employees, was in charge of a research project on personal health. The project was carried out in the 1980s. The researcher was subsequently employed at a research institute. During his employment at the research institute, the researcher enters into a collaboration with the university on a new research project. The project will examine the health of the same people after 20 years. The research institute and the university have jointly drawn up the protocol and applied for funding for the new project. In connection with the research project, blood

samples have been taken, which have subsequently been

a biobank at the analysis institute. The analysis institute stores the information in the biobank after the end of the project for independent future research.

The analysis institute and the university are joint data controllers for the processing of personal data that takes place as part of the new research project. The research institute is an independent data controller for the personal data in the biobank, as they process these for their own purposes. The university is the data controller for the original project from the 1980s.

3.2.6 Steering group

A university enters into a research collaboration with several municipalities. A steering committee is set up with one representative from each party. The steering committee jointly decides the framework for the project in the project description. The stakeholders agree to use the university's existing research platform, which is operated by an external supplier. Each party transfers information to the platform for the purpose of joint research.

There is joint data responsibility for the processing carried out using the research platform, as the actors have jointly prepared the project description and have chosen to use the research platform for processing personal data. The municipalities that decide to make use of the research platform so that the data can be processed for the agreed purpose also participate in determining the means of processing. In the agreement on joint data responsibility, the actors can agree that the university, on behalf of all actors, enters into a data processing agreement with the supplier for the operation of the research platform. The fact that the actors have internally agreed that one actor handles the operation of the database does not affect the distribution of roles. On the contrary, the actors are obliged to enter into a joint arrangement where they determine who is responsible and for what, such as entering into a data processing agreement, etc. with the external supplier of the research platform.

3.2.7 Writing group and internal work distribution I

An analysis institute is to be part of a large research project with a Dutch university, a Canadian university and a Finnish health authority. A researcher from the research institute came up with the idea for the project and prepared a description and protocol. The other stakeholders have commented on the protocol and approved the content. Data from a number of registers will be analyzed and samples will be taken from the participants.

A writing group is established with a researcher from the analytical institute, a doctor from the Finnish health authority and a researcher from the Canadian university. Together with the other members of the writing group, the researcher from the analysis institute helps decide which data to use and how to analyze it. The researcher, together with the others, decides which samples to take from the participants and how to analyze them.

The researcher from the analysis institute will be responsible for analyzing the data from the external registers. In practice, a group from Finland and Canada is responsible for taking samples from the individuals and analyzing them. The actors from the Dutch university are not part of the writing group, but contribute data to the writing group by mutual agreement. It is jointly decided that all results will be entered into the IT system normally used by the Finnish Health Authority on an ongoing basis.

The actors are joint data controllers for data processing in the research project. This applies even if the actors do not perform the same amount of tasks and it has been decided to use the IT system from the Finnish authorities. The Dutch university is an independent data controller for the transfer of personal data to the joint controller.

3.2.8 Writing group and internal work distribution II

A research institute must be part of a large research project with an interest organization, a region and a university on research into a specific type of cancer. The research institute must be involved because the research institute has data that the other stakeholders would like to use for the project. The actors have jointly initiated and developed the protocol for the project. In addition to the analysis institute's data, information from the region's patient records will also be included in the research project.

A writing group is established with a researcher from the university, a doctor from the region and a representative from the interest organization. The researcher from the analysis institute is not part of the writing group. However, the researcher from the analysis institute has an ongoing dialogue with the writing group about how the data should be processed and analyzed in order to be included in the project.

The actors are joint data controllers for the research project, as they have jointly defined the objective of the project, drawn up the protocol and initiated the project. This applies even if the actors do not carry out equal amounts of the tasks. The processing of personal data carried out by the region as part of patient treatment is not part of the joint data responsibility. It is the region itself that is the data controller for this part, as the region pursues a separate purpose in this connection.

3.2.9 Research collaboration between region and university

A region has initiated a research project because they want to investigate a hypothesis. The region has defined what it wants to investigate, but does not carry out the research project itself and has no influence on how the project is specifically carried out. The region therefore enters into a collaboration with a university researcher, as their expertise is crucial for the actual organization and implementation of the analysis. The region and the university collaborate on the external circumstances of the project in terms of finances and schedule, but the organization of the actual analysis is carried out by the university researcher. The region subsequently receives the raw data and the experimental results. According to the university researcher, conducting the analysis will lead to new knowledge that can be published.

There is no joint data responsibility, even though the region and the university have jointly collaborated on the external circumstances of the project. Regardless of the region's overall definition of what is to be studied in the research project, the university decides on the detailed organization of the study.

The university is thus an independent data controller for the research project, including for the disclosure of raw data to the region. The university will also be an independent data controller for the processing of personal data that will take place in connection with the researcher's publication of the results of the research project. The researcher has no independent role under data protection law, but is simply part of the university. The region is the independent data controller for the raw data received by the region after the trial has been completed.

If the region has commissioned an analysis where the region has control over how the research project is specifically carried out, including what information is collected and what analysis methods are used, and the researcher from the university works solely under instructions, the university will be the data processor for the region.

3.2.10 Analysis Institute's research project with region and European university

A researcher at a research institute decides to conduct a research project. The project is to be carried out in collaboration with doctors from a region and a researcher from a European university. The research will be based on available data from the region's registries and patient records. In addition, questionnaire surveys will be conducted among the trial participants, who will also have a number of blood tests taken.

The analysis institute and the doctors from the region jointly determine the overall content of the project, which is approved by the researcher from the European university. The researcher's approval of the project is a prerequisite for the implementation of the project. The overall content of the project is described in the protocol, including the register data to be used and the method. The parties have agreed that only the research institute and the region will jointly create the questionnaires and enrich the results of the questionnaire survey with data. The parties have also agreed that only the analysis institute and the region determine how the blood samples are to be analyzed.

The parties have agreed that the researcher at the analysis institute is responsible for analyzing the register data. The analysis must be quality checked by the researcher from the European university. It is agreed that the region is responsible for the practicalities of

distributing and collecting the questionnaires, taking blood samples and analyzing the samples.

The researcher from the European university will help quality check the analysis of the data from the registries. The researcher from the European university will also co-author an article to be published based on the research. The remaining parts of the research project are carried out jointly by the research institute and the region.

The research institute, the region and the European university are joint data controllers for the research project, as they have jointly decided why and how the personal data in the research project is processed. It does not affect this assessment that the parties have internally agreed that they each handle different parts of the processing of personal data. On the contrary, the parties are obliged to enter into a joint arrangement where they determine who is responsible and for what. The researchers from the European University and the research institute have no independent role under data protection law, as they are part of the European University and the research institute respectively. The region is an independent data controller for the processing of personal data that takes place in the registers and patient records and for the disclosure that takes place for the project.

3.3 Disclosure in connection with research projects

3.3.1 Disclosure from the Danish National Archives

A public authority has decided to carry out a research project and in this connection applies for access to data from the Danish National Archives' collections. The Danish National Archives is not part of the research project.

The Danish National Archives is the independent data controller for the disclosure of personal data to the public authority. The authority is the independent data controller for the processing of the personal data received in connection with the research project.

3.3.2 Researchers' access to data from the National Archives' collections

At present, the Danish National Archives cannot provide facilities for processing digital data from the Danish National Archives' collections. This means that researchers often process digital data via facilities that they themselves have access to, or via another authority's service for researchers (e.g. Statistics Denmark's or the Danish Health Data Authority's research service).

The Danish National Archives is the independent data controller for the disclosure to the researcher. The institution to which the researcher is affiliated is the independent data controller for the processing of personal data carried out in connection with the research project. The researcher has no independent role under data protection law, but is part of the institution to which he or she is affiliated. It does not affect this assessment that the Danish National Archives' granting of access to archives is based on an application to the individual researcher. If the other authorities' service consists solely of making infrastructure available for the analysis, while the decisions about the purpose and organization of the research are made by the research institution, the authorities are data processors.

3.3.3 Disclosure of information from your own patient records

A group of researchers from Region A have a research project. The research project is based on information from patient records. The project will use information from patient records from all five regions. The other regions do not participate in the execution of the project, but only pass on information from their own patient records.

Region A is the independent data controller for the research project, as the researchers from Region A alone have planned and decided the purpose of the project and carry out the project alone. Each region is independently data controller for the disclosure of information from its own patient records. Region A becomes an independent data controller for the copy of the patient records that are disclosed for use in the research project. This is thus a transfer between independent data controllers.

3.3.4 Publication of results

A pharmaceutical company and a hospital have planned and decided to conduct a study. As part of the study, a researcher at the pharmaceutical company prepares an article for publication in a journal. A doctor employed by the hospital who has been part of the study co-authors the article. As part of the peer-review process, the journal requires that information from the study is made available and transferred to the journal so that the analyses from the study can be verified by external peer reviewers.

The pharmaceutical company and the hospital are joint data controllers for the processing of personal data in the study, as the parties have jointly organized and conducted the study. The doctor is part of the hospital and has no independent role under data protection law. The same applies to the researcher at the pharmaceutical company.

The pharmaceutical company and the hospital are joint data controllers for the disclosure of personal data to the journal. The journal is an independent data controller for the processing of personal data in connection with the publication and verification. The former peer reviewers are independent data controllers, as they are not subject to the journal's instructions when they verify the results of the study.

3.3.5 Disclosure for research project and authorship

A company applies results from a previous research project to a new research project. The new research project is led by a European authority and a Canadian university. The company only provides personal data from its previous research project. The data is shared with the European authority and the Canadian university. The European authority and the Canadian university have jointly prepared a project description, which contains a description of the purpose, method, framework for the research project, the data used, etc. The company has only seen the description of the project... The company's work consists of the company subsequently participating in the quality check of the analysis of the data, whereby they receive personal data. The company's quality check is not binding on the European authority and university and should therefore only be seen as feedback. The project description for the research project, including the other methods chosen, is not determined by the company. However, an employee from the company must co-author the scientific article to be written on the basis of the research project.

The European authority and the Canadian university are part of a joint data responsibility for the research project. The company is not part of the joint data responsibility, as the company does not have a controlling influence on the project and the company's service consists solely of non-committal feedback. The co-authorship of the article does not change this assessment. However, the company is an independent data controller for the transfer of personal data from the company to the project.

3.4 Buying data and ordering services

3.4.1 Buying data

A university receives a data set from a company against payment in order to carry out a research project. The university only organizes the implementation of the research project, including hypotheses, data collection, etc. However, the company requests the university to enter into a data processing agreement with the company so that the university becomes the data processor, as the company wishes to retain the rights to the data set.

Even if the university agrees to the company's demands and enters into a data processing agreement with the company, the university is an independent data controller. This is because it is not possible to escape the controller's obligations (or become a controller) by drafting a contract in a certain way if the division of roles assumed in the contract is not supported by the facts.

Since the university has only organized research projects, the university is not a data processor for the company. Therefore, the fact that the university has signed a data processing agreement with the company does not affect the division of roles.

3.4.2 Ordering between regions

A researcher from Region A has planned and decided to carry out a research project. A statistician from Region B is to carry out some specific statistical calculations and analyses in the project. The calculations and analyses are concretized and decided by the researcher from Region A.

Region A is an independent data controller, as Region A alone decides how personal data is to be processed in the project. This is done by drawing up the protocol, planning and deciding how and with which methods, such as calculation methods and statistical analyses, the project will be carried out. As Region A has ordered a specific statistical analysis from Region B, the statistician from Region B processes personal data for Region A's purposes and under Region A's instructions. Region B is therefore a data processor for Region A in connection with the performance of the statistical analyses.

3.4.3 Outpatient clinic and analysis

In a research project, a university enters into an agreement with a research institute for the research institute to interview a number of people. The university has developed the interview framework and questionnaire that the research institute uses. The individuals are also asked to provide a blood sample to an outpatient clinic, which analyzes the samples and sends the analysis results and the sample itself to the university. The outpatient clinic is subject to professional standards and legislation on how blood samples etc. should be analyzed.

The analysis institute is a data processor on behalf of the university, as the analysis institute must apply the interview framework and questionnaire prepared by the university. The analysis institute thus acts under the instructions of the university. The outpatient clinic is also a data processor for the university, as the outpatient clinic acts on behalf of and under instructions from the university. This does not change the fact that the outpatient clinic is subject to certain professional standards that the outpatient clinic must follow when conducting blood sample analyses, as these standards do not prevent the clinic from analyzing certain blood samples in a specific way, for example by examining for the presence of selected substances.

3.4.4 External funding and data processor

A university college receives funding from a foundation for a research project. The university college defines the purpose of the project and the methodology. To help with some of the analytical work in the research project, the university college enters into an agreement with a company. The company has no influence on why and how the personal data is processed. The researchers at the university college instruct the company on how to process the personal data and for what purpose.

The university college is the data controller, as the university college alone has decided on the organization of the research project. The company is the data processor, as the company has not had any influence on the organization of the project, but acts under instructions from the university college. The foundation has no role under data protection law, as the foundation only contributes funding and has no other influence on the project.

3.4.5 Questionnaire survey

A research institution wishes to make use of a service offered by a survey agency. The service concerns the recruitment of respondents for a survey in a research project. The agency has a panel of members who answer surveys on an ongoing basis for a fee. The agency's service consists of providing the research institution with contact details of members who can participate in a survey. The research institution pays the agency for the service, and the agency has its own system for payment of the individual member. It is a prerequisite for the agency's payment of the member that the agency has information about who actually participates in the survey.

Both the research institution and the agency are independent data controllers for their respective parts. The research institution's purpose for processing the data of its members is to carry out the survey, and the research institution decides how this data is to be processed. The agency's purpose of processing is to provide the applicable service, and the agency also decides how the data will be processed.

When the agency discloses contact details of members who can participate in the research institution's survey and the research institution correspondingly returns information about the members who actually participate in the survey to the agency, this constitutes a transfer between two independent data controllers.

However, if the agency had been commissioned to conduct the survey on behalf of the research institution, and the research institution had developed the questions and selected the participants, the agency would be the data processor.

3.4.6 Patient treatment with medicine

A doctor in a hospital wants to treat a patient with a product from a pharmaceutical company. The product is not approved in the country in question. The doctor applies to the pharmaceutical company to supply the product to the patient in question, and the pharmaceutical company agrees. The doctor reports the patient's name and any side effects of the product to the pharmaceutical company.

The hospital is an independent data controller as it processes personal data for the purpose of patient treatment. The doctor has no independent role under data protection law, but is part of the hospital. The pharmaceutical company is an independent data controller for the processing of information about any side effects reported by the doctor.

3.5 Pharmaceutical companies

3.5.1 Clinical study I

A pharmaceutical company has planned and decided to conduct a research project and approaches a hospital. The principal investigator at the hospital participates as the primary investigator, providing input and approving the protocol, including what information is to be collected and what equipment is to be used for the analysis. The principal investigator also approves the study report and the results presented therein before they can be published. The hospital subsequently wishes to submit the trial results to a scientific journal for publication, where the principal investigator will be listed as an author. Publication requires that the project's raw data is shared with the journal for validation. The principal investigator is responsible for ensuring that all doctors and nurses participating in the trial at the hospital follow the protocol. The pharmaceutical company trains the principal investigator on the protocol and other relevant information before the start of the study. The investigator, doctors and nurses are legally allowed to deviate from the protocol if and when they deem it to be in the best interest of the trial participant. At the same time, the doctors enter the information in the patients' medical records.

The pharmaceutical company and the hospital are joint data controllers for the processing of personal data carried out as part of the research project. This is because they pursue the same purpose - carrying out the research project - and have jointly decided how, including with which equipment, the data is processed. The hospital is an independent data controller for the processing that takes place when information is entered into patient records. The researcher does not have an independent role under data protection law, but is part of the hospital.

The hospital is an independent data controller for the transfer of personal data to the journal for the purpose of publishing articles. Regardless of the authorship of the principal investigator, the principal investigator does not have an independent role under data protection law as he or she is part of the hospital. The pharmaceutical company and the hospital are not joint data controllers for this disclosure to the journal, as it is only the hospital that discloses data for its own purposes to the journal.

3.5.2 Clinical study II

A pharmaceutical company has planned and decided on a research project. A hospital is required by law to conduct research. A doctor at the hospital has registered in a database of research institutions that want to collaborate with the pharmaceutical industry to conduct research. The pharmaceutical company is required to pay 120% remuneration in relation to the hospital's actual expenses. The hospital secures part of the physician's salary by the physician entering into a research collaboration with the pharmaceutical company and

fulfilling its obligation

laid down in legislation. The pharmaceutical company writes the protocol and secures approval from the relevant authorities. The doctor collects data and enters it into the pharmaceutical company's systems. The pharmaceutical company sends a copy of the entered data to the doctor, which the doctor and hospital are required by law to keep.

The pharmaceutical company is an independent data controller. The doctors conducting the research project will generally be subject to professional and legal obligations. These obligations may mean that the doctors will not be able to follow instructions on the processing of personal data. The hospital will therefore not be able to take on a role as a data processor in connection with the research project. The hospital is therefore also an independent data controller, even if the doctor's processing of personal data (also) takes place in accordance with a research protocol planned and determined by the pharmaceutical company.

3.5.3 Hospital's research project with drug

A doctor at a hospital wants to do a research project. For the project, they need to use medicine from a pharmaceutical company that agrees to provide the medicine free of charge to the doctor. The doctor writes the protocol and secures the relevant approvals. The pharmaceutical company provides input to the protocol, including the choice of data platform for storing personal data. Funding and resources at the hospital are made available for the project, such as data collection and analysis, and the pharmaceutical company does not incur any costs. The doctor is responsible for the results and any publication, and the pharmaceutical company provides input for any articles. At the end of the study, the doctor sends a copy of the raw data and results to the pharmaceutical company, which can be used for further research.

The hospital is an independent data controller for the processing of personal data that takes place as part of the execution of the research project and for the disclosure of personal data to the pharmaceutical company. This is because the doctor at the hospital has initiated the research project and drawn up the protocol. The doctor has no independent role under data protection law, as the doctor is part of the hospital. The pharmaceutical company and the hospital are not joint data controllers, regardless of the pharmaceutical company's input to the protocol. This is because the pharmaceutical company's input to the protocol is not essential for the processing of personal data and the pharmaceutical company has no influence on the project. The pharmaceutical company is an independent data controller for the processing of personal data carried out after receipt of the data.

3.5.4 License to sell product

Pharmaceutical company A has a product that has been launched in a number of countries. Pharmaceutical company A enters into a collaboration with pharmaceutical company B to apply for marketing authorization in the countries where pharmaceutical company B is established and where pharmaceutical company A is not established and therefore not authorized. As part of the agreement, all clinical data related to the product is transferred from pharmaceutical company A to pharmaceutical company B. Pharmaceutical company B uses information from pharmaceutical company A to apply for marketing authorization in the countries where company B is established for the purpose of selling the product in these countries. Pharmaceutical company A receives a fee based on the number of products sold.

Pharmaceutical company A and pharmaceutical company B are both independent data controllers. This is because pharmaceutical companies are subject to legislation that requires them to submit relevant trial data in connection with the submitted marketing application and to subsequently report, among other things, adverse reaction data to relevant health authorities after obtaining a marketing authorization. In addition, pharmaceutical companies are subject to supervision by the drug regulatory authorities in connection with the marketing of products under an authorization obtained. Pharmaceutical company B will therefore often have to make an independent decision on how to handle the information in question and will in practice not be able to follow any instructions from pharmaceutical company A.

Pharmaceutical company B subsequently uses the information related to the product together with their own data to further develop their own product as a combination product. Information from pharmaceutical company A's studies is included as part of the application to the authorities for approval of their own product.

Pharmaceutical company B remains an independent data controller, as pharmaceutical company B has decided its purpose and means of processing the data.

3.5.5 Subsidiary and hospital roles

A pharmaceutical company in Denmark decides to conduct a study and approaches its subsidiary in Germany, which contacts a hospital in Germany. The pharmaceutical company prepares the protocol. The subsidiary ensures translation into the local language and approval of the project by the German authorities and scientific ethics committee. The subsidiary enters into a collaboration agreement with the hospital. Patients at the hospital participate in the trial if they agree, and patients follow the standard treatment at the hospital. The patient treatment is decided by the doctors at the hospital and the doctors use a drug produced by the pharmaceutical company. Relevant data is transferred from the patient records to a system controlled by the pharmaceutical company. Data is analyzed, reported and published by the pharmaceutical company.

The pharmaceutical company is an independent data controller, as the company has decided the purpose of the treatment, the execution of the study and the means of treatment in the protocol. The data controller has no role under data protection law, as the subsidiary does not process any personal data in connection with its conclusion of the cooperation agreement with the hospital or obtaining the relevant regulatory approvals. The doctors conducting the research project will generally be subject to professional and legal obligations. These obligations may mean that the doctors will not be able to follow instructions on the processing of personal data. The hospital will therefore not be able to take on a role as a data processor in connection with the research project. The doctors do not have an independent role under data protection law, but are part of the hospital.

3.5.6 Data collection and storage

A company initiates a research project and develops a study protocol. The company enters into a collaboration with a hospital where a doctor collects data according to the protocol. The doctor enters data about the study participants, who are patients at the hospital, into a system provided by the company. At the end of the project, the company sends an extract of the collected trial data to the doctor. By law, the doctor and the hospital are responsible for storing this data, which is kept together with other relevant information at the hospital.

The company is an independent data controller, as they have initiated the project and drawn up the protocol for it. The doctors conducting the research project will usually be subject to professional and legal obligations. These obligations may mean that the doctors will not be able to follow instructions on the processing of personal data. The hospital will therefore not be able to take on a role as a data processor in connection with the research project. The hospital in this example is therefore also an independent data controller, even though the company has planned and decided on the research project. The doctor has no independent role under data protection law, but is merely part of the hospital. If professional and legal obligations do not prevent the doctor from following instructions - as the activity (entering data into a system) takes place independently of patient treatment - the hospital would be a data processor under the circumstances.

3.6 Hardware and software

3.6.1 Common data platform

Several universities enter into a research collaboration and choose to establish a common data platform. The universities have jointly chosen which data to process in connection with the project. While the parties involved have a common purpose for the processing and have jointly chosen to use the data platform in question, they each have different licenses. This means that the access to data on the platform varies from university to university.

The universities are joint data controllers as they pursue the same purpose. In addition, the universities have jointly decided what data is collected and how it is processed, including by using the common data platform. This division of roles is not changed by the fact that the parties have different licenses for the platform.

3.6.2 Cloud I

Several regions decide to enter into a research collaboration, which they jointly fund. A cloud-based platform is used to process the data. The cloud service is standardized and the terms of service are determined unilaterally by the provider. The regions have limited possibilities to customize the service or change the terms of use of the service.

The regions are joint data controllers, as they have jointly initiated and financed the project. The regions have also jointly decided how the data will be processed when using the cloud-based platform for processing data. Provided that the cloud provider does not process the personal data that the regions transfer to the platform for its own purposes and thus only processes the data in accordance with the regions' instructions, the provider is a data processor for the regions. It does not change this assessment that the cloud service has limited customization options or that the cloud provider has set the terms of service. This is because even though the cloud service offers a predefined service, it is the regions that, based on a detailed description of the service, make the final decision to actively authorize the way in which the processing is carried out.

3.6.3 Cloud II

A company and a hospital have jointly decided and planned a study. As part of the study, there is a need to manage daily activity, communicate and exchange documentation between the company and hospital staff. The company provides a cloud solution that can be used for the project. A hospital employee is given individual access to the cloud solution, which is paid for and managed by the company but provided by an IT company. After completing the study, the hospital employee's access to the cloud solution is closed. The hospital subsequently receives relevant information to be stored as part of the study documentation.

The company and the hospital are joint data controllers for the processing of personal data carried out as part of the study and for the subsequent storage of the data as study documentation. This is because the parties have jointly decided why and how personal data in the study is processed. It does not affect this assessment that the parties have internally agreed that the company will make the cloud solution available. On the contrary, the parties are obliged to enter into a joint arrangement where they determine who is responsible and for what, e.g. who enters into any data processing agreements. The IT company is a data processor on behalf of the joint controllers, as the IT company is subject to the controllers' instructions.

3.6.4 Cloud III

Through a product, a company has collected personal data that a university wants to use for a research project. The company stores the personal data on a cloud platform that the university can access.

The company and the university are independent data controllers for the disclosure and collection of personal data through the cloud platform, respectively. The university has not had any influence on the collection and subsequent storage of the personal data in the cloud platform, and there is therefore no joint data responsibility between the parties for this part of the processing.

3.6.5 Using an app for data collection directly related to the study

A pharmaceutical company and a hospital have jointly decided and planned a study using an app developed and maintained by the pharmaceutical company. The app is accessed on a tablet made available to trial participants by the pharmaceutical company. Information that the trial participants enter into the app is uploaded to a cloud solution provided by a

IT company. The pharmaceutical company has entered into a contract with the IT company for the operation and maintenance of the cloud solution. The IT company is not allowed to use the data for their own purposes.

During the study, participants enter their health data daily into the app, which the hospital can monitor on an ongoing basis. The pharmaceutical company does not have access to data from the app or tablet during the study. Data from the app is subsequently transferred by the IT company to the pharmaceutical company, which analyzes the data. Data from the app is also transferred by the IT company to the hospital for storage in their study documentation.

The pharmaceutical company and the hospital have jointly decided on the purpose and means of processing personal data in the study and are therefore joint data controllers for this processing. The IT company is the data processor on behalf of the joint controllers, as the company is subject to instructions and does not process the personal data for its own purposes.

Roles in research projects

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