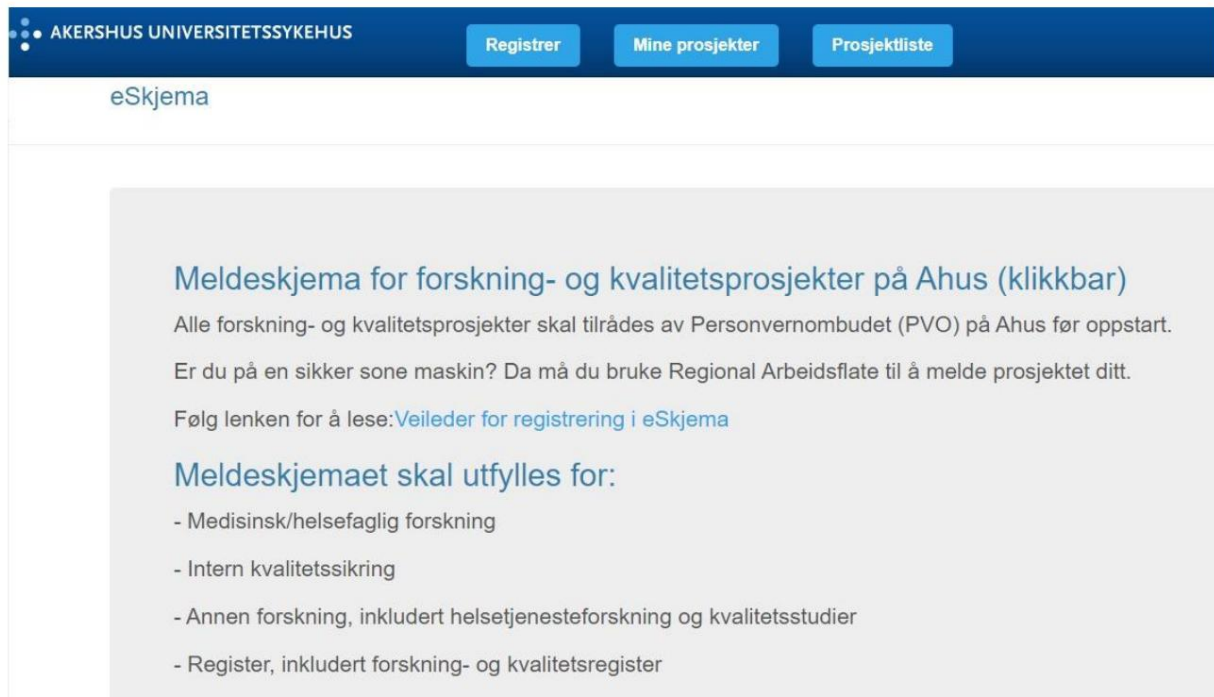


# Guide for registration of quality and research projects in eSkjema



**Meldeskjema for forskning- og kvalitetsprosjekter på Ahus (klikkbar)**

Alle forskning- og kvalitetsprosjekter skal tilrådes av Personvernombudet (PVO) på Ahus før oppstart.

Er du på en sikker sone maskin? Da må du bruke Regional Arbeidsflate til å melde prosjektet ditt.

Følg lenken for å lese: [Veileder for registrering i eSkjema](#)

**Meldeskjemaet skal utfylles for:**

- Medisinsk/helsefaglig forskning
- Intern kvalitetssikring
- Annen forskning, inkludert helsetjenesteforskning og kvalitetsstudier
- Register, inkludert forskning- og kvalitetsregister

## Questions?

### Contact us at:

[forskning.personvern@ahus.no](mailto:forskning.personvern@ahus.no)

(completion of the eSkjema and questions about the start of projects)

or

[eskjema@ahus.no](mailto:eskjema@ahus.no)

(technical use, error messages, input)

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## 1) Briefly about the eSkjema

### 1.1) What is eSkjema?

eSkjema is an electronic reporting form that has been developed at Ahus, and which takes care of a number of control aspects associated with the implementation of research projects:

- Registration of quality and research projects (including change notices and closing announcements)
- Requirements for an overview of the processing of personal data according to GDPR (Article 30)
- DPIA self-declaration
- Internal control and options for extracting reports to both Ahus managers and agencies.

In addition, the eSkjema provides an overview of projects for the project manager, head of department, privacy research, and Ahus employees in general. All research and quality projects must be advised by the Personal Data Protection Ombudsman (PVO) at Ahus before commencement.



Figure 1: overview of the various tabs in the eSkjema. Under the **"Register"** button , you can start the registration of a new project. Under **"My projects"**, the project manager can see an overview of all his started and registered projects, here you can also see whether the department manager has approved the project and what the status is with the data protection officer (PVO). Under **"Project list"** you can see an overview of all projects at Ahus that have been reported in the eSkjema. Under **the "Department manager page"**, the department manager can see an overview of all registered projects in his own department.

### 1.2) Who will use the eSkjema?

The notification form must be completed for:

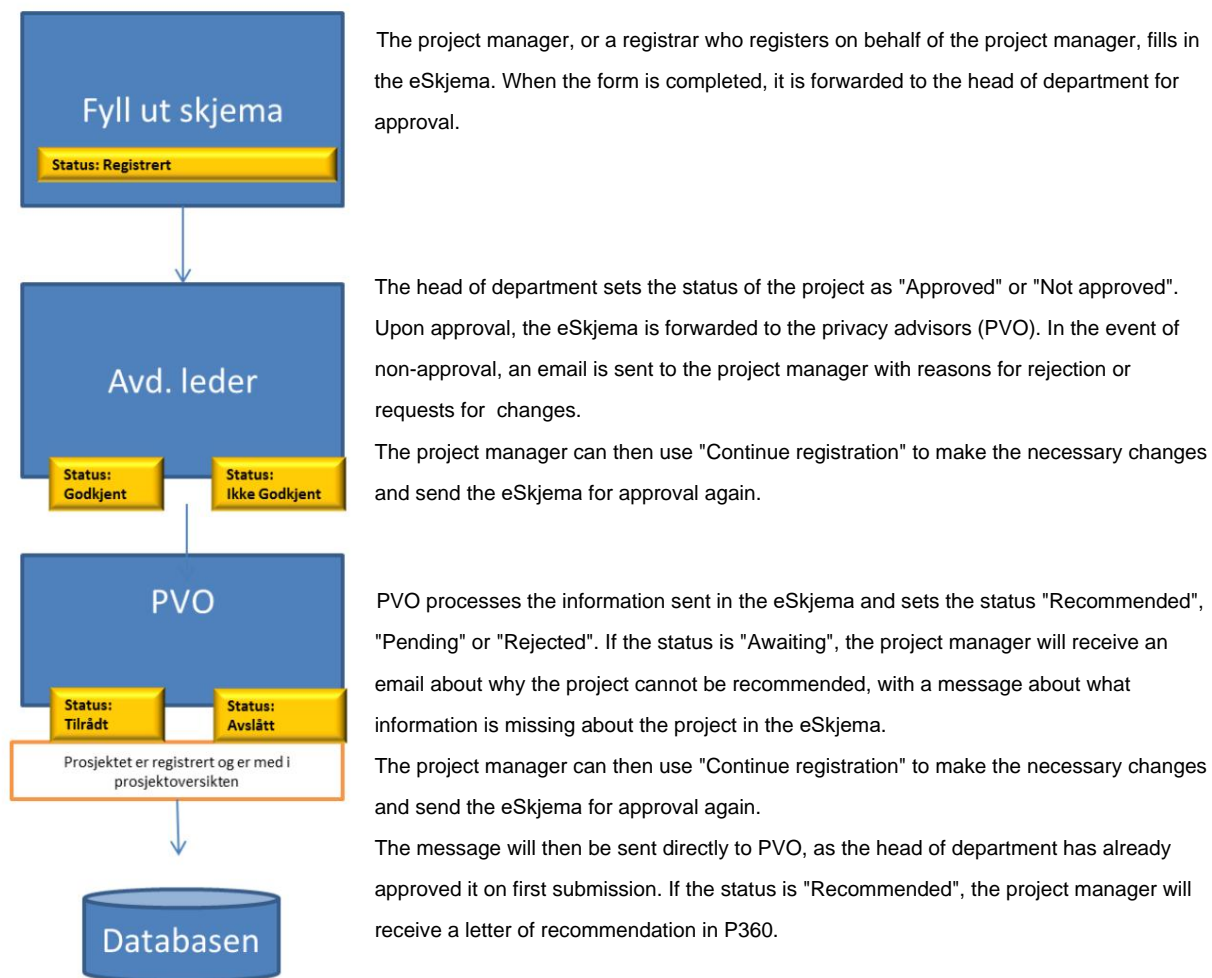
- Medical/health research
- Internal quality assurance
- Other research, including health service research and quality studies
- Registers, including research and quality registers

Project managers who must register new projects, send change notices or project termination notices must use the eSkjema.

It is possible to register projects on behalf of a project manager. It is only possible to have one registrar per project, in addition to the project manager himself.

All projects at Ahus that are sent in eSkjema require approval from the head of department. If the head of department is himself the project manager, approval will be sent to the head of department's immediate manager (most often division/clinic director), and follow the management line.

### 1.3) Case flow in the eSkjema



### 1.4) General information about eSkjema

- The eSkjema is not adapted to all projects, fill in as well as possible and feel free to use available free text fields where possible.
- There is help text in many of the fields, press the question mark to bring up more information.
- Many of the fields are mandatory. If a mandatory field is not relevant, "not applicable" is used.
- To register a project in the eSkjema, the project manager or registrar must be connected to the network associated with Ahus.
- Project registration is linked to the username of the project manager at Ahus. It is therefore important that the e-mail and user name of the project manager are correctly registered in the fields provided, to ensure that correspondence about case management reaches the project manager.
- The project manager can temporarily store completed information in the eSkjema by using the button for "Temporarily saved" at the bottom of the form.
- All relevant documentation must be stored and dispatched to the project's case number in the case archive system of Ahus; Public 360, before registration and submission in the eSkjema. For more information about Public 360, see point 2.5.
- It is the project manager's responsibility to ensure that the information registered in the eSkjema is correct.

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## 1.5) Where can you get help?

Questions related to filling in the eSkjema and questions about the start of projects can be directed to privacy and research advisers at [forskning.personvern@ahus.no](mailto:forskning.personvern@ahus.no) or by phone 476 82 544 (telephone hours Monday – Friday 09.00 – 15.00)

Questions related to technical use, including error messages and other feedback to eSkjema, should be addressed to [eskjema@ahus.no](mailto:eskjema@ahus.no)

## 2) Guidance for completing the eSkjema

### 2.1) How to register a project in the eSkjema

Use a PC with Ahus login and the following address: <http://eskjema.ad.ahus.no/>



Before registering a new project in the eSkjema, the necessary documentation for case management must be filed on the project's file in P360. This is so that the data protection officer will have the necessary information available to be able to make a recommendation about the project. For more information on P360 see point 2.5.

#### ***For project manager/ registrar:***

To register a new project, press "**Register**" in the top tab. Fill in the necessary information about the project. If you need more information about completion, see section 2.5. The project can be temporarily stored before it is sent to the head of department. The status of the project will therefore be either "**Temporarily saved**" or "**Sent**". Upon submission, an automatic e-mail will be sent to the head of department that a new registration has been received in the eSkjema.

#### ***For head of department (how to process a registered project):***

- 1) Go to the "**Department manager page**".
- 2) Press "**See details**" for the project in question, and a new page will appear.
- 3) Press "**Change status**" and a new page will appear.
- 4) Change the status in the drop-down menu (Approved/Not approved) and press "**Update**".
- 5) The project has now been forwarded for assessment by the data protection representative.

#### 2.1.1 How to see the status of a registered project

The project manager can see the status of the registered project himself, under "**My projects**". By pressing "**See details**" an overview will open. Here, under "**Status department manager**" it will either say "**Not processed**", "**Approved**" or "**Not approved**".

- If the status is "**Not processed**", the head of department has not approved the project yet, and the project will therefore not be visible to PVO.
- If the status is "**Approved**", the head of department has approved and the project will be visible to PVO which can start counseling.
- If the status is "**Not approved**", the head of department has not approved the project.

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Saksnr	Prosjekttittel	Status prosjektleder	Status Avdsleder	Status PVO
2023_9	Prosjekt 1 - test	Sendt inn	Ikke behandlet	Registrert
2023_20	Prosjekt 2 - test	Sendt inn	Godkjent	Tilrådet

Figure 2: example of status projects. Under the button **"My projects"**, the project manager can see an overview of all his/her started and registered projects, as well as see whether the department manager has approved the project and what the status is with the Data Protection Commissioner (PVO). In the projects above, project 1 has been submitted but has not yet been approved by the head of department, while Project 2 has been approved by the head of department and recommended by PVO.

## 2.2) How to send a change notification in the eSkjema

Before submitting a notice of change, the necessary documentation for case management must be filed on the project's file in P360.

### For project manager/registrar:

A separate **"Notice of change/Termination"** button is used. This functionality becomes available after the data protection officer has recommended the project, and the **"Notification of changes/Termination"** button then appears under **"See details"** for the specific project.

When you have pressed the **"Notification of changes/Final notification"** button, a new page will appear where all project information will be visible - here you can register changes to the project. A free text field will also appear, but this is only for entering briefly what the change applies to, to help PVO in its case management. *The actual change must therefore be entered directly in the current eSkjema field to be changed.*

Figure 3: Change notification in eSkjema. In the case of a change notification, you tick the selected change, briefly fill in information about the change in the free text field, and then go through the form to make the change in the correct place. The change notice is then sent to the head of department for approval.

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After submission of the change notification, it must be approved by the head of department, and approval must be available before the change notification can be processed by the data protection officer.

**ATTENTION!** It is only possible to send one change notification at a time. This is to avoid multiple change notifications being sent at the same time, as this will cause the different change notifications to overwrite each other, and the information will not be visible in the eSkjema. If you have submitted a change notification, and it has not been processed by the head of department/PVO, the button for "**Change notification/Final notification**" will be deactivated until the change notification has been processed.

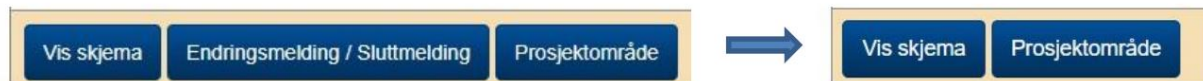


Figure 4: Deactivating the change notification button. Under "**See details**" you will find the button for "**Notice of change/termination**". If you have submitted a change notification, the button for "**Change notification/end notification**" will be deactivated. The button will be available again as soon as the head of department and PVO have approved and recommended the changes. This is to ensure that you only submit one change notification at a time.

**For head of department (how to process a change notification):**

If the change notification is unprocessed, it will be visible in **red font**. As soon as the change notice has been approved/processed by the head of department, it will be marked in black.

- 1) Go to the "**Department manager page**".
- 2) Press "**See details**" for the project in question, and a new page will appear.
- 3) Under "**Change notification/Final notification**" (top table), press "**See details**" for it specific notice of change.
- 4) Press "**Change status**" and a new page will appear.
- 5) Change the status in the drop-down menu (Approved/Not approved) and press "**Update**".
- 6) The change notification has now been forwarded for assessment by the data protection representative.

### 2.2.1) Change project staff:

To add new project employee(s), available field(s) are used. If there is a need to add more than 10 project employees, use the "+" button (located to the right of the table) to make more fields available.

An upper limit of a total of 15 internal project staff has been set. If you want to add more than these 15, you submit a change notification in the eSkjema to change project employees, but write the names of the new project employees in a separate list, which must be uploaded in P360.

To remove project employee(s) from the project, set the role of the relevant project employee(s) to "**Delete**". This is done by selecting "**Exit**" from the "**Role**" drop-down menu.

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### 2.2.2) Change the end and deletion date:

To change the end and deletion date, use the available fields in the eSkjema. When you change the date for the end of the project, the field **"Project deletion date"** will automatically be reset to zero and must be filled in again. For more information on the difference between end and deletion dates, see **section 2.5**.

### 2.2.3) Change/add a registrar to a project in the eSkjema: A registrar

can be added and register new projects, project changes and/or final notices on behalf of the project manager. It is only possible to have one registrar per project, in addition to the project manager.

**To add a registrar:** A registrar can register on behalf of the project manager the first time the project is reported in the eSkjema. If the project manager has registered the project himself, but wants a registrar to have access, the project manager must send an email to [eSkjema@ahus.no](mailto:eSkjema@ahus.no) with the name of who will act as registrar.

**To change the registrar:** The project manager must send an email to [eSkjema@ahus.no](mailto:eSkjema@ahus.no) with the name of who will be the new registrar.

Reminder that it is the project manager's responsibility that the information in the eSkjema is correct.

## 2.3) How to apply for storage areas

### 2.3.1) For new project areas:

Project area ordering is taken out of the eSkjema, and must be ordered either in the Research Portal or via Min Sykehuspartner. Links to supervisors appear when the project has been recommended by PVO, and will then appear under the **"Project area" page**.

### 2.3.2) For already existing project areas: Under the **"Project area"**

**page** in the eSkjema, there will be an overview of which project areas have been approved and who has access. If an area has only been ordered in one of the zones (either (N) or (V)), it is possible to send a new order if necessary to create an area in the other zone.

It must be stated which research server at the Ahus project area is to be created in, select the zone for the project area, either on Research Einstein (N) or Research Sensitive Data Curie (V). Click on **"Send"**.

The analysis department at Ahus ([analyse@ahus.no](mailto:analyse@ahus.no)) receives the order form and is responsible for creating and managing access. The project manager receives feedback by e-mail when the project area is created.

When a change of project staff is recommended by PVO, the project manager in the **"Project area" page** must remove/add to the check box for access for relevant project staff. When the form is submitted, an automatic e-mail will be sent to the Analysis department, which can assist with granting or removing access to project area(s) for the respective project staff.



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## 2.4) How to send a termination notice in the eSkjema

**NOTE!** Before the termination notice is registered in the eSkjema, all information in the project must be updated and any change notices must be advised by the data protection officer. In addition, any final notices to the relevant authorities, for example REK and SLV, must be sent.

In the main, the procedure for notification of termination follows the same as for processing notification of changes.

### **For project manager/registrar:**

Here, a separate **"Change notification / End notification" button is used**. This functionality becomes available after the data protection officer has recommended the project, and the **"Change notification / End notification" button** then appears under **"See details"** for the specific project.

When you have pressed the **"Change message / Final message" button**, a new page appears where all project information is visible; there is a separate tick box for **"Final notification"**.

After submission of the termination notice, it must be approved by the head of department, and approval must be available before the termination notice can be processed by the data protection officer.

### **For head of department (how to process a termination notice):**

- 1) Go to the **"Department manager page"**.
- 2) Press **"See details"** for the project in question, and a new page will appear.
- 3) Under **"Change message / Final message"**, press **"See details"** for the specific message.
- 4) Press **"Change status"** and a new page will appear.
- 5) Change the status in the drop-down menu (**Approved/Not approved**) and press **"Update"**.
- 6) The message has now been forwarded for processing by the data protection representative.

When PVO has recommended the final report, the project will be locked for new changes to the eSkjema.

## 2.5) Detailed explanations and help text for the fields in the eSkjema

### 2.5.1) Public 360 number

Public 360 (P360) is the electronic case archive system used at Ahus. All documents belonging to a project must be stored on the same file in P360.

Before a new case is created on the project, a search must be made in P360 to check that it has already been created a case. Use relevant words such as project manager or all or part of the name of the project in the search.

If the project is not included, a new case is created with naming as described in the guide to registration in P360 (attached EQS document 32429).

The documents that are archived under the project's file in P360 are used for processing submitted eForms.

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### 2.5.2) Research and data manager

The research and data manager is the institution that has overall responsibility for the project, and must have the necessary prerequisites to fulfill its duties. The managing director at Ahus is the data controller for all research projects at Ahus. The Director for Research and Innovation is delegated authority as data and research manager at Ahus, and is administratively responsible for research projects where Ahus is the institution responsible for research. The data and research manager must arrange for the projects to meet requirements for professional and scientific soundness, privacy, information security, etc.

### 2.5.3) Project manager/internal manager at Ahus

The project manager is a physical person responsible for the day-to-day running of the research project, and who has the necessary research qualifications and experience to be able to fulfill the project manager's duties under the Health Research Act.

In projects where an external institution is responsible for research, and Ahus is a collaboration partner or contractor, there must be a local project manager who is employed by Ahus.

### 2.5.4) Head of department at Ahus

The head of department is the overall person responsible for the project in the department, and must facilitate proper planning, organisation, implementation and completion of the project. The head of department must always approve the project before applications are submitted, both internally and externally. When the eSkjema has been completed, it is automatically sent to the stated head of department for approval. The head of department must approve the project before it is forwarded to the data protection officer. If the project manager is also a department manager, the application must be sent to the division/clinic director.

### 2.5.5) Project title

The name of the project, both scientific, English and Norwegian, must be the same in relevant applications and forms where the project is registered. For example, use the same title as in the application to the Regional Committee for Medical and Health Research Ethics (REK) and eSkjema to PVO. Both Norwegian and scientific titles will be included in the public project register in REK. Many projects with long titles often use an acronym or abbreviation.

### 2.5.6) Project purpose

Use of personal data must be necessary based on an expressly stated purpose. The purpose must be stated in the project description, protocol and letter of consent.

If the project is subject to an REK application, the purpose in the eSkjema must be the same as in the REK application.

It is the purpose that determines which legislation regulates the project.

If the purpose is medical and healthcare research that is carried out using scientific methodology to acquire new knowledge about health and disease, the project must also be assessed by REK.

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In health service research, scientific methodology is used to acquire knowledge about the performance of the health service.

The purpose of the quality project is to check that the performance of the health service actually produces the expected results, in order to improve diagnostics and treatment of patients.

With internal quality assurance, the purpose is to ensure quality or improve the hospital's internal operations.

### 2.5.7) Project period

The project period stated must correspond to the decision from REK, and is the period when the project actively begins until the project ends. There is a requirement in the Health Research Act to store research data for a period after the end of the project, this so that external authorities can ensure verification

of published results. Data must not be used in the period between the end of the project and the deletion date for research data. The end of the project is the last date for research activities, which means that before the end of the project both the research and all publications based on the research must be completed.

### 2.5.8) Other project information

Before the project can be initiated, the project manager must decide to which project category the project belongs: Medical/health research, quality assurance, other research including health service research and quality studies, registers including research and quality registers.

Project category is defined based on the main purpose of the project. The project manager must then obtain all required approvals and documentation, which the selected project category requires. See Table 1 below for more information.

Table 1 Category	Requires approval/advice from:		
	WHO	RECs	SLV
Medical/health research projects Clinical drug trials	x	x	
Testing of medical equipment Internal quality assurance Other research	x	x	x
	x		
(incl. health service research and quality projects)	x		
Research and quality registers	x		

Some processing of personal data will involve a high risk for the privacy of the individual. In these cases, a privacy impact assessment (DPIA) will also have to be carried out, where measures must be found to remedy the risk for the individual. This must be assessed by PVO and approved by the data controller before the register is created or the project starts.

Research collaboration is registered if the project involves collaboration on the initiation, implementation and completion of the project with other departments or divisions at Ahus, within the health region,

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between different regions, between countries internationally, or if the project is part of a European research collaboration with funding from the EU.

By project staff is meant everyone who does something active in the project - has access to research data o.l.

### 2.5.9) Privacy

#### *Treatment basis*

Regardless of the purpose of the project, there must be a processing basis (authorized by law) in order to be able to process personal data.

The processing grounds can, for example, be:

- Consent from the data subject, cf. the personal data protection regulation article 6 no. 1 letter a and article 9 no. 2 letter a (when processing special categories of personal data, including health data). • Dispensation from the duty of confidentiality granted pursuant to Section 29 of the Health Personnel Act and/or Sections 19b or 19e of the Health Register Act. Depending on the purpose of the project, the basis for processing according to the regulation could be Article 6 no. 1 letter c and e cf. no. 3, and Article 9 no. 2 letter g, h, i (cf. no. 3) and j. This will vary with the purpose of the project, including whether it is research or quality assurance.
- Internal quality assurance with exceptions from the duty of confidentiality, cf. the Health Personnel Act § 26 and the Patient Records Act § 6. The basis for processing is the Personal Protection Regulation article 6 no. 1 letter c and no. 3 and article 9 no. 2 letter h and no. 3.

#### *Consent*

It is desirable that consent is obtained as far as possible in all projects. For healthcare research and "other research", the main rule is that written consent must be obtained. If consent is not to be obtained, the project manager must apply for a dispensation from the obligation of confidentiality, including an exemption from the consent requirement. Decisions where a dispensation is granted are stored on the case number in Public 360.

#### Requirements for the consent:

Consent must be informed, voluntary and documentable. Information must be provided about the project's purpose, method, risk, discomfort, consequences and other matters of importance for the validity of the consent.

The information provided must be adapted to the individual's requirements, for example if the person in question is a minor. Consents must be kept locked in a restricted room, but separately from other project data.

For **internal quality assurance projects**, as a general rule, there is no requirement for consent from the data subject, although this should be strove for. Please note that patients have the opportunity to object to personal data being processed, also internally, this is then recorded in the medical record.

#### *Personal information*

If you are unsure whether the information the project will process is personal information, please contact privacy advisor/privacy representative for guidance.

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Directly identifiable information is name, social security number and other information which, viewed in isolation, says something about who a person is. Indirectly identifiable personal information is information which, in combination with other information, can identify a person. In cases where directly identifiable characteristics have been replaced with a code, fictitious name etc., one speaks of pseudonymised personal data. As far as possible, the information shall be stored pseudonymised. If the information cannot be stored pseudonymised, this must be justified.

It takes a lot before information can be considered anonymous. Please note that answers to questions in questionnaires, where each answer to a question appears anonymous, can together make the information indirectly identifiable - for example where there are questions about age, ethnicity and gender.

Furthermore, please note that information where there is a code key, code list etc. in your own or another institution will never be anonymous information.

#### *Who performs the extraction of information from registers or records at Ahus*

All postings in journals and other registers are logged. It is therefore important that it is a person who has a valid legal basis who makes the withdrawal into a concrete project where Ahus is a participating institution. That is, the project manager or a project employee. The project manager cannot delegate this responsibility to a random employee in the department. It must be possible to describe why the person has posted.

#### *How the personal data is stored and processed*

See EQS routine "Household - Implementation - Storage, archiving and deletion of health and personal data", ID number: 33743.

#### *External storage*

If the information is to be stored in an electronic data collection solution or "other storage area", which has not already been approved by Ahus, the solution must be risk assessed (ROS analysis) by the owner of the solution. The project manager is responsible for obtaining the risk assessment from the owner of the solution.

The risk assessment must be entered on the case number in Public 360. The information security manager at Ahus must assess and approve the risk assessment, before the data protection representative can make a recommendation to the project. In clinical commissioned studies where a pharmaceutical company is the sponsor and data controller for all data in the eCRF, the sponsor is also responsible for preparing and having available a ROS analysis.

#### *2.5.10) Disclosure of information Ahus is a cooperating party*

Before personal data can be disclosed to another legal entity, it must be verified that the external legal entity has a legal basis for requesting the relevant information to be disclosed. This also applies if the name and social security number have been replaced with a code number, or if the information itself will give the identity of the individual.

Where consent has been obtained, the patient must always be informed of the disclosure in the consent form.

There must be agreements with institutions that process personal data on behalf of Ahus.

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In some cases, additional guarantees must be obtained before delivery, e.g. that a risk assessment, a DPIA must be carried out and/or guarantee statements must be obtained where the cooperating party is located in a third country.

For questions, contact privacy advisors.

### 2.5.11) Biobank

#### *Person in charge*

Each research biobank must have a responsible person with medical or biological education at a higher degree. At Ahus, as a general rule, the project manager must be responsible for the biobank. If another institution is responsible for the biobank, it is the one stated in the REK application that must be as responsible.

#### *Prior approval from REK*

Creation of a biobank requires prior approval from REK. Prior approval also applies for new, changed or extended use of an existing research biobank, and if biological material from a diagnostic biobank is to be used.

The duration of the biobank follows from REK decisions. If no specific duration is given in the decision from REK, the project duration must be stated.

#### *Genetic investigations*

Completion of this point must correspond to the description in the research protocol and what is stated in the REK application and in the REK decision.

#### *Transfer of human biological material to and from abroad*

Human biological material from a biobank can only be sent out of the country or brought into the country after approval from REK. This requires entering into a "material transfer agreement", EQS id 17970.

### 2.5.12) Any additional information for the project

To be filled in as needed, and to assist the case management of the project at privacy research.

### 2.5.13) Privacy impact assessment (DPIA) - self-declaration

According to Article 35 of the Personal Protection Regulation, a DPIA must be carried out if it is likely that data processing will entail "a high risk for the rights and freedoms of natural persons". This means that in several cases a DPIA will have to be carried out in case of project changes. By

review and answer the points in the self-declaration, the privacy risk in the project is assessed, and this will further give an indication of whether it is necessary to carry out a full DPIA. If there is uncertainty about whether a DPIA should be carried out or if help is needed to carry out a DPIA, research and privacy advisers can be contacted.