Standards for the responsible conduct of research at the Faculty of Health

Fundamental guidelines and requirements designed to safeguard freedom of research and to support all personnel involved in research at the Faculty of Health in planning, conducting and concluding a research project in a transparent, credible manner.

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Background

Research integrity and freedom of research are central values at Aarhus University. Everyone who contributes to research at Aarhus University is expected to integrate these principles for responsible conduct of research into their daily activities as a matter of course. These principles include honesty, responsibility, reliability, objectivity, impartiality, fairness, openness and responsible management of the resources with which one has been entrusted.

This means that everyone who contributes to research at the Faculty Health must be familiar with and comply with:

1. Aarhus University's *Policy for research integrity, freedom of research and responsible conduct of research*

2. Aarhus University's *Rules regarding advice on responsible conduct of research* and Aarhus University's *Rules for the Research Practice Committee* (handling suspicions of breach of responsible conduct of research at Aarhus University)

3. AU's *Instruction for research data management* (currently under development).

In addition, everyone who is engaged in research at the Faculty of Health must be familiar with and comply with the instructions in these *Standards for the responsible conduct of research at the Faculty of Health*. The Faculty of Health's standards lay down fundamental guidelines and requirements designed to assist the individual researcher and research group at the faculty in planning, conducting and concluding a research project in a transparent and credible manner and to safeguard freedom of research.

The faculty management team is responsible for ensuring that personnel at the Faculty of Health is familiar with these standards, and that they are integrated into the practice of the faculty's research groups. The faculty management team is also responsible for laying down the necessary guidelines for handling research plans, protocols and data storage as well as the content of collaboration agreements.

1. From project initiation to project conclusion – ensuring responsible conduct of research

This section presents a range of fundamental guidelines designed to provide support for planning, executing and concluding research projects in a transparent, credible manner. Each section is accompanied by a note highlighting *requirements* that must be complied with. Each section also states where further information can be found if needed.

1.1. Preparing the research project

In the case of projects involving a number of parties, it is important to harmonise expectations regarding the overall project management and to describe this in the project description before the research project begins.
A project description, which must also be approved by the Health Research Ethics Committee, must comply with the requirements of the Danish health research ethics committees act (videnskabsetiske komitélov) as summarised in a list detailing requirements in regard to content that is available on the Danish National Committee on Health Research Ethics Committee (NVK) website.
The project description or protocol must include the following information:

- Who is participating in the project and which functions and responsibilities have been assigned to the various participating persons/parties
- Who is assuming primary responsibility for the project as a whole
- Who is managing the project and the project manager's function
- Which functions and responsibilities are being delegated to external project participants
- The data flow [1]and responsibility for the data processes described
- Drafting of publications and crediting of authorship in accordance with international guidelines as described in *AU's policy for research integrity, freedom of research and responsible conduct of research*. (See also section 3
- How and by whom any disputes are to be resolved
- Who is responsible for funding the project, and who is responsible for applying for funding.

When partners from outside AU participate in a research project, a collaboration agreement must always be drafted for the parties involved in the project. The collaboration agreement must state that all parties agree to comply with Aarhus University's guidelines for responsible conduct of research and freedom of research. The collaboration agreement must include a description of how the project is to be managed that includes the information stipulated above. The legal aspects of all collaboration agreements must be approved by the Technology Transfer Office (TTO) at Aarhus University, and by the head(s) of the department(s) with which the project is affiliated.

TTO reviews the legal aspects of the following:

- Publication clauses

[1]The concept 'data flow' is used here to refer to the processing of research data during and after the project's 'lifetime', including collection, registration, storage, sharing/transfer, etc. of data during and after the project.

- Data flow
- Clauses regarding rights, including who has the right to dispose of data and any patent rights
- Confidentiality clauses
- Substitution and insurance clauses
- Disputes, including where and how any differences are to be resolved
- Exclusivity clauses.
- Publicity (e.g. publication of sub-reports or statements in general).

1.2 General guidelines regarding health science research projects

- The project description and other necessary documents, including contracts and permits must be completed before a project begins. This also applies to pilot experiments on human subjects.
- The project description must be drafted in a manner that makes it possible to repeat the experiments, even several years later. This means that complete traceability is required with regard to the origin and generation of data.
- In connection with some projects, it will be necessary to add descriptions of any departures from the original project plan in the relevant passages. In connection with clinical trials, it will thus be necessary to describe any amendments to the trial in a new version of the protocol, which in most cases will require separate approval by the authorities.
- In connection with clinical trials, errors and discrepancies must be documented in the data management system or on the Case Report Form (CFR). Any amendments to the project description must be clear, dated and accounted for, and the identity of the person responsible for the amendment must be stated.
- If any of the collected data is omitted from the final publication, this must be stated clearly and accounted for in connection with the final report and in the event of publication.
- The majority of research projects at the Faculty of Health involve animal experimentation, human subjects research or research on human biological material, which are governed by special legal requirements. See the descriptions below.
- Projects which may potentially lead to the development of biological weapons are subject to the approval of the Centre for Biosecurity and Biopreparedness.

1.3 Animal experimentation

- Anyone conducting experiments on animals must comply with the provisions of the Danish animal experiments act (lov om dyreforsøg, in Danish only), and no such experimentation may be initiated without prior authorisation from the Danish Animal Experiments Inspectorate. In accordance with the Danish clinical trials of medical products act (lov om kliniske forsøg med lægemidler, in Danish only), no clinical trials of medical products may carried out on animals without prior authorisation from the Danish Medicines Agency. In addition, a report must be submitted to the Danish Medicines Agency in the event that adverse effects occur during such experiments.

- If alternative methods of achieving the knowledge that the animal experimentation is intended to produce exist, as a general rule, applications for authorisation to perform an animal experiment will be denied.

- Another requirement is that the smallest possible number of animals be used, and the necessary

steps must be taken to ensure that the animals are subjected to as little suffering as possible.

- Finally, the law stipulates that animal experimentation must be of significant benefit, and that the benefit of the research must outweigh the suffering inflicted on the animal.

- Anyone involved with animal experimentation must have completed a mandatory animal experimentation training course.

1.4 Research with human subjects

This refers to projects involving experiments on live-born human individuals, human gametes intended for fertilisation, fertilised human eggs, embryos and fetuses, tissues, cells and genetic material from humans or deceased persons.

All research projects involving human subjects or human biological material are required to comply with the Helsinki Declaration. To the extent that the project falls under the scope of the Danish health research ethics committees act, it must be applied for and granted by the Health Research Ethics Committee in the region in which the principal investigator is employed. Empirical projects, including observational studies and surveys which require ethical approval but which fall outside the scope of the health research ethics system, may be submitted to the Research Ethics Committee at Aarhus University.

In addition, informed consent, consent by proxy or regulatory authorisation must be obtained in connection with all research projects involving human subjects or human biological material.

All studies under section 1.4 must also be reported to either Aarhus University's internal research project register or to Central Denmark Region's internal research project register (guide under development).

1.4.1. Health science research projects that must be approved by the Health Research Ethics Committee

All studies under 1.4.1 must be authorised by the Health Research Ethics Committee on the background of an application. An application for authorisation of the research project (a notification) must be submitted to the Health Research Ethics Committee in the region in which the principal investigator is employed. The committee will then assess whether the proposed project is in compliance with the Danish health research ethics committees act. The legal obligation to apply for authorisation from the research ethics committee system applies to all clinical investigations, regardless of whether or not the equipment used bears the CE mark.

A new act on clinical trials of medicinal products has been adopted in Denmark under which new medicinal product research ethics committees will be established. The act is expected to come into force simultaneously with the EU regulation on clinical trials that will revise the rules for clinical trials throughout the European Union.

1.4.1.1 Interventional studies

All health sciences research projects under section 1.4.1.1 must also be reported to an approved register.

With regard to registration, WHO defines an interventional study (clinical trial) as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes". All interventional studies must be registered concurrently with or before the first human participant is assigned to the trial on the WHO International Clinical Trials Registry

Platform (ICTRP), or with ClinicalTrials.gov http://www.clinicaltrials.gov/. When applications for the authorisation of clinical trials of medicinal products or medical devices in phase II-IV are submitted to the Danish Medicines Agency, these trials are automatically registered in the EU Clinical Trials Register. Phase I trials and other trials (for example, involving alternative medicine, hypnosis, exercise and so on) can be registered at ClinicalTrials.gov, for example. The Trial Nation unit (formerly Én Indgang) can provide assistance with registering trials in ClinicalTrials.gov.

Interventional studies involving medicinal products or medical devices under sections 1.4.1.1. a and 1.4.1.1 b must also be approved by the Danish Medicines Agency on the background of an application.

The legal obligation to apply for authorisation from the Danish Medicines Agency applies to all clinical investigations of medical devices with and without CE marking if the objective of the investigation is to use the medical device for a new purpose. The Danish Medicines Agency is the supervisory authority in regard to the technical/scientific assessment of the clinical investigation of the device. On the Danish Medicines Agency website on medical devices, an introduction to clinical investigation of medical devices is available, along with instructions on how to submit an application for authorisation to conduct clinical investigations of medical devices.

Both the Danish National Committee on Health Research Ethics and the Danish Medicines Agency have guidelines for drafting project descriptions for clinical studies. A single overall project description covering all of these points in detail may be prepared.

1.4.1.1. Interventional studies of medicinal products

Clinical trials of medicinal products are defined as any investigation intended to determine or test the clinical, pharmacological and/or other pharmacodynamic effects of medicinal products on human subjects, including the identification of any adverse reactions, or to investigate their pharmacokinetics in order to gain knowledge about their safety or efficacy for humans.

As a general rule, clinical trials of medicinal products initiated and conducted at the Aarhus University Hospital or another hospital in Central Denmark Region must be reported to the Central Denmark Region research project registry, and in case of PhD projects under AU, must also be further reported to AU (guide under development).

Clinical trials of medicinal products must comply with the Danish GCP (Good Clinical Practice) ministerial order, in Danish only. Researchers can contact the GCP unit at Aalborg University Hospital and Aarhus University Hospital for assistance and monitoring of trials.

If the trial includes laboratory analyses performed in a research laboratory, the laboratory should as far as possible comply with the OECD's guidelines on Good Laboratory Practice (GLP). If the laboratory analyses are performed at a hospital laboratory, the same requirements apply at a minimum, but as such analyses performed will often be accredited, as such they will implicitly be in compliance with the GLP.

1.4.1.1 b Interventional studies of medical devices

A clinical investigation of medical devices on humans is defined as any investigation involving humans that aims to determine or test the safety or performance of medical devices. The device tested may be a new medical device or a familiar device already being marketed in Denmark.

Clinical investigations involving medical devices must comply with the standard DS/EN ISO 14 155 (the equivalent to ICH-GCP for medical devices). The GCP Unit at the university hospitals in Aalborg and Aarhus may be contacted in connection with investigations of medical devices that must be authorised by the Danish Medicines Agency on the background of an application.

The Development of health apps and software is classified as a medical device, and must comply with the European Commission's Guidance and Danish ministerial order 1263 of 15 December 2008 on medical devices (bekendtgørelse 1263 af 15/12/2008 om medicinsk udstyr). Read more in the Danish Medicines Agency's guide.

1.4.1.1 c Other interventional studies

Examples include dietary intervention trials (for example, cod liver oil), the effect of hypnosis, the effect of exercise on pain, etc.

1.4.1.2. Biological material

The collection of human biological material for a biobank in association with a specific health research project (including a clinical trial) must be approved by the Health Research Ethics Committee.

The collection of human biological material for biobanks requires the informed consent of the trial subject.

The use of previously collected human biological material in connection with a new project requires the authorisation of the Health Research Ethics Committee as well as the informed consent of the trial subject to the new project, unless a waiver with regard to consent is granted by the Health Research Ethics Committee.

Only licensed medical doctors, nurses or certified laboratory technicians trained in the extraction of human biological materials for scientific or medical purposes may extract biological material in accordance with the conditions set out in the authorisation. This rule does not apply to non-invasive collection of biological fluids, such as semen, saliva, milk and so on. The principal investigator is responsible for ensuring the confidential, safe and appropriate storage and ethical use of the biological materials, respect for donor confidentiality and appropriate disposal of the material.

Transfer of biological materials to a third party must be approved by the Danish Data Protection Agency.

1.4.2. Health science research projects that do not require approval by the Health Research Ethics Committee

Health science research projects under sections 1.4.2 that do not require approval by the health research ethics committee must be reported to Aarhus University's internal research project register or to Central Denmark Region's internal research project registery. Applications for approval of empirical projects, including observational studies and surveys that involve collecting data from individuals, may be submitted to the Aarhus University Research Ethics Committee.

1.4.2.1. Data from patient records

In trials involving the collection of information from patient records, the disclosure of such information must be approved by the Danish Patient Safety Authority.

1.4.2.2. Interview/questionnaire

The objective of interviews and/or questionnaires is to collect knowledge from or about the respondents within the field of the research project.

1.4.2.3. Data from registers

Register-based research is defined as non-interventional research based on analysing health data (electronic data and biological materials) from existing databases and registers/biobanks.

1.4.2.4 Electronic health data

Register-based research projects involving electronic health data must be reported to the Central Denmark Region internal research project register if the research project is based in Central Denmark Region, or to Aarhus University's internal register of research projects if the research project is based at Aarhus University (guide under development).

Collecting sensitive personal data from an existing legal database[2] must be approved by the database administrator and with the associated conditions for disclosure as laid down in applicable data protection legislation.

1.4.2.4 Human biological materials

Human biological materials include human tissues, blood, cells, genetic material, skin, nails, hair, eyes and other human organs, faeces, including meconium (the feces of newborn infants) and human bacteria, as well as human bodily fluids, including saliva, semen, urine and the like.

Research involving individually identifiable biological material that has already been collected (biobank (register) research) must be reported to the Health Research Ethics Committee in the region in which the principal investigator is employed, with the exception of research trials involving cell lines (laboratory cultures or the like). However, research involving fertilised eggs, stem cells and stem cell lines must always be reported.

Material or information from a clinical biobank or a research biobank may only be used in a research project with an authorisation from the Danish Data Protection Agency. Applications to the Danish Data Protection Agency can either be made via Aarhus University's internal research project register or Central Denmark Region's internal research project register. In addition, as a general rule, the consent of the research subject from whom the biological material was extracted must be obtained, unless the Health Research Ethics Committee has granted an exemption from the consent requirement. Finally, Vævsanvendelsesregistret (the tissue utilisation register) must be consulted to ensure that the human subject has not registered a decision that their biological material may not be used for research.

A waiver from the consent requirement may be granted by the Health Research Ethics Committee on the background of a concrete assessment, on condition that the project does not represent a health risk or have the potential under the given circumstances in general to burden the test subject in other ways, or if it would be impossible or disproportionately difficult to obtain informed or proxy consent.

[2] Examples include national registers or local databases approved for future research.

2. Data

Scientific data are to be collected and stored in accordance with current statutory rules and other provisions. Data are defined as all material collected systematically for research purposes, including electronic data from registers, surveys or interviews, images, human material such as blood or tissue or material from animals, including biobanks.

The general guidelines for responsible conduct of research with regard to data are as follows:

- The data flow [3]must be outlined in the project description
- All experimental protocols, plans and strategies for experiments/studies, notes, laboratory books, data and primary material must be stored for five years after the completion of the research project, except where this conflicts with other legislation or professional standards. As stipulated in section 3.2 of AU's policy and the Instruction for research data management (guide under development)
- There must be open access to material on which publications are based (the FAIR principles), except where this conflicts with legislation or contractual obligations. According to section 3.2 of AU's policy
- Any corrections made to data during data collection and data recording must be clearly indicated and accounted for in order to ensure that all changes or additions are completely transparent, thereby ensuring data traceability.

The EU's General Data Protection Regulation (GDPR) and the Danish Data Protection Act (the data protection legislation) describe the fundamental principles that must be fulfilled in connection with all processing of personal data. The Danish Data Protection Agency is the central independent authority which monitors compliance with the data protection legislation.

- More detailed guidance on how to store and secure personal data is available on Aarhus University's website on data protection and data protection legislation.
- A general security criterion is the requirement to pseudonymise data whenever possible in the given context. The security requirements for pseudonymised data [4] are less strict.
- In accordance with the data protection legislation, data (including biological material) may not be stored longer than is necessary for the purpose for which they were collected and must be anonymised after the purpose, including requirements regarding storage, has been achieved. There are different requirements with regard to how long experimental data must be stored, including personal data, after the completion of the project. See for example the Danish clinical trials of medical products act (Lov om kliniske forsøg med lægemidler), which stipulates a storage period of 25 years. See also the Instruction for research data management (guide under development)
- After the purpose has been achieved and the storage requirement fulfilled, it must not be possible to identify individual data subjects in the experiment. Personal data must be subsequently

[3] See footnote 1.

[4] When personal data are pseudonymised, the data are keycoded so that they cannot be attributed to a specific data subject without the use of additional information that is stored separately. Pseudonymised data are still covered by the data protection legislation.

deleted[5], anonymised or submitted to the National Archives.

- In connection with research involving personal data, registration and authorisation are mandatory. These requirements are described above under the individual types of project. Further information is available from TTO at Aarhus University.
- Data must be stored at the institution where the research was conducted. However, where relevant any conditions set by project funders must be taken into account. Individually identifiable data may not be stored on a personal computer, and paper print-outs of such data must be locked away securely. With regard to data storage, the rules for storage laid down in the data protection legislation and other supplementary legislation must be complied with.

3. Publication and authorship

In connection with publication of the results of a completed research project, the following applies:

- All results from completed studies should be published – including any negative or inconclusive results.
- Results are to be published in the most timely manner possible. It is acceptable that patent applications may give rise to some delay.
- In connection with submission to a journal, data should be anonymised, so that it is not necessary to apply to the Danish Data Protection Agency for approval of the journal's use of the data.
- All authors, including supervisors, must meet all of the authorship criteria.

At a minimum, an author's contribution to the scientific publication must consist of:

1. Substantial contributions to the conception or design, data collection, analysis or interpretation of data, and
2. Substantial contributions to the drafting of the publication.

All authors must approve the final research publication which is submitted for peer review and the final manuscript which is subsequently published. Aarhus University expects anyone who accepts authorship to also assume responsibility for the scientific integrity of the work as a whole. The degree of responsibility of each author is assessed in relation to their individual role in the research project and in relation to their expertise, experience, seniority, supervisory role and other relevant factors, cf. AU policy.

Anyone who is credited as an author must fulfil the authorship criteria, and anyone who fulfils the authorship criteria must be credited as an author.

Relinquished authorship, ghost authorship, honorary authorship, guest authorship and planted authorship all constitute a breach of responsible conduct of research.

- The criteria used to establish the order of authors in the list of authors must be agreed on by all project partners at the beginning of the project and may subsequently be revised by joint agreement.
- Contributions from project partners and intellectual contributions from others should be

[5] When personal data are pseudonymised, it is not possible to identify the data subject, either directly or indirectly. Anonymised data are not covered by the data protection legislation.

recognised and cited in the text or under 'Acknowledgements' with a wording approved by the persons being acknowledged. Financial or other substantial material aid received for the project must also be stated. Specific guidelines apply to public access to information about private funding of research at state-owned research institutions – see private funding of research (in Danish).

- Before submission of a manuscript, a joint signed authorship statement detailing the nature and extent of every author's contribution may be prepared if the terms of authorship are not already regulated by the collaboration agreement. At a minimum, the statement should be retained by the primary author.
- It is recommended that the principal investigator (PI) take special responsibility for ensuring that the publication is based on credible research. Some journals require that one or several authors guarantee that the entire work was composed in a credible manner, and that this guarantee is stated in the publication.
- Covert redundant publication, i.e. identical or nearly identical publications, including translated into other languages, is never acceptable. On the other hand, secondary publication (ex.: English language article subsequently published in Danish in the Journal of the Danish Medical Association, or vice versa) is permitted when undertaken openly. Use of the same data or subsets hereof in different publications does not constitute double publication, provided any data overlap between a previous and a current work is clearly stated to full disclosure with regard to reviewers and readers.
- It is crucial that the contents of the article correspond to the summary provided in the synopsis/abstract.
- The rules outlined above must also be complied with in connection with publication through other channels than journals.

Special authorship rules exist for large multi-author groups, previously termed multi-centre studies. When a large multi-author group is responsible for conducting the studies, the group must identify the persons who will be directly responsible for the manuscript from the outset. These persons must meet the authorship criteria as defined above, and these authors will be the main responsible authors. Journals frequently cite the remaining members of such groups under the acknowledgements. (For more details, please see ICMJE. Multi-author groups, p. 3.)

3.1. Guidelines for reporting

To increase the uniformity and improve the quality of the reporting of various types of studies, it is a good idea to consult the international guidelines in this area, which are available from the Equator network.

3.2 Conflicts of interest

All authors must state any conflicts of interest. Conflicts of interest arise when authors or their institutions, reviewers or editors are affected by financial or personal interests, which may influence their judgement and give rise to bias. Potential conflicts of interest may be present even in cases in which an individual believes that an issue does not influence his or her work on a manuscript.

Editors and proofreaders may not work on their own manuscripts or manuscripts from their own organisation, and they should be completely independent of any private companies with interests in the area (economic, advisory board or similar). This rule is intended to ensure that no changes are introduced in the final proof of the manuscript without the approval of the authors.

4. Collaboration agreements with industry and other institutions

4.1 Types of collaboration

As a researcher you may become involved in many different types of collaboration. Based on the contents and conditions for the relationship, collaborations can be categorised under three main headings:

1: Unrestricted grants. In connection with this type of collaboration,the funder will typically select an area/topic to fund, but as a rule, no conditions are imposed on the grant.

2: Commissioned research/income-generating activities. In this type of collaboration, a consultancy service is provided. This means that all rights belong to the external party, and special rules apply (with regard to income-generating activities) for the calculation of the grant based on market prices, as all costs, direct as well as indirect, must be covered.

3: Subsidised research. In this type of collaboration, the university may co-finance the projects, provided that the project has documented research interest for the researchers involved. According to the guide to external funding 2013 (Instruks Eksterne Midler 2013), the head of department is responsible for ensuring that a genuine research interest is present. In this type of collaboration, both parties contribute in different ways, and a formal agreement must be concluded in regard to the parties' rights to the results of the project.

In regard to all types of collaboration, it is important that the parties' rights and obligations are clear. For this reason, it is necessary that a written agreement be concluded for each collaboration describing the parties' contributions, division of responsibilities and rights.

Particular in collaborations with industry and special interest organisations and the like, it is necessary to draft a written collaboration agreement that lays down the parties' responsibilities, rights and obligations in the project, including which party was responsible for initiating the project, who developed the protocol and who has responsibility for collecting material and data, interpreting data, ownership of data, drafting of the manuscript and presentation of results to the public. In this way, a cooperation agreement aids in the harmonisation of the parties' mutual expectations and must also contribute to guaranteeing freedom of research. The agreement must contain a description of how the project is to be financed in addition to a roadmap for the publication of the results. Finally, it must be stated that the parties agree to comply with Aarhus University's guidelines for responsible conduct of research.

All research projects that rely on external funding in Central Denmark Region must comply with the rules in the FAS regulations (in Danish only) regarding externally financed projects in Central Denmark Region, including rules regarding accounts and personnel.

TTO can provide more information, advice and guidance. Aarhus University has general guidelines for collaboration agreements (generelle retningslinjer for samarbejdsaftaler, in Danish only). Correspondingly, the university hospitals have adopted a set of joint guidelines (in Danish only) for cooperation agreements.

4.2 Regulatory requirements in regard to collaboration with companies

The Danish health act (sundhedsloven) lays down so-called 'association rules', that require public sector healthcare professional who conduct research or consultancy for pharmaceutical or biotech companies to report these associations, regardless of whether they receive remuneration for the work.

Consultancy work performed by the healthcare professional on a private basis and in a privately owned

company are also covered by the rules of association.

The healthcare professional must personally
• Report the activity, or
• Apply for authorisation for the activity from the Danish Medicines Agency, depending on the nature of the collaboration.

The association rules will continue to be supplemented by applicable rules on marketing.

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Appendix 1. Overview of the approval process for human subjects research

Overview of the approval process for studies with data

Health science research projects that must be approved by the Health Research Ethics Committee							
	Danish Medicines Agency	**Health Research Ethics Committee (REC)**	**AU Research Ethics Committee** (in cases in which the project falls outside REC system)	**The Danish Patient Safety Authority**	**Data supplier**	**AU's register or CDM's register[6]**	**The Danish Data Protection Agency**
Interventional studies with medicinal products	X	X				X	
Interventional studies with medical devices	X	X				X	
Other interventional studies		X				X	
Health science research projects that do not require approval by the Health Research Ethics Committee							
Data from patient records				X		X	
Register-based research, data from national databases and/or registers					X	X	
Where also processing outside the territorial scope of the GDPR – plus approval Data Protection Agency							X
Where publication in a recognised journal or similar – and data not anonymous – plus approval Data Protection Agency							X
Observational studies as well as interviews and questionnaires			X			X	

[6] Research projects with patient data can either be registered in CDM's or AU's research project register depending on affiliation.

Overview of approval of trials with biological material

Register-based research, databases and/or registers with biological material	Creation of a biobank	Research from biobank (disclosure)
1) Research biobank (specific research purpose)	• Health Research Ethics Committee • Informed patient consent to the collection of biological material for the biobank • AU register or CDM register	• AU register or CDM register • The Danish Data Protection Agency
2) Biobank for future research (research project not defined)	• Separate informed patient consent to the creation of a biobank for future research • AU register or CDM register	• Health Research Ethics Committee • Informed patient consent for a new specific research purpose, unless a waiver has been obtained from VEK for the new research purpose) AU register or CDM register • The Danish Data Protection Agency