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

Fundamental guidelines and requirements designed to support the individual researcher or research group in planning, conducting and concluding a research project in a transparent and credible manner.

Background

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, transparency 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. Aarhus University's basic principles for responsible conduct of research and research freedom in regard to collaboration with external parties.

4. Instructions for storage and management of research data.

Everyone who is engaged in research at the Faculty of Health must also be familiar with and comply with the instructions in the faculty's Standards for the responsible conduct of research at the Faculty of Health.

The faculty management team is responsible for ensuring that personnel at the Faculty of Health are familiar with these standards, and that they are integrated into the practice of the faculty's research groups. The faculty management team is furthermore responsible for laying down the necessary guidelines for handling project descriptions, 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, carrying out and concluding research projects in a transparent, credible manner.

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 be approved by the regional health research ethics committees and possibly the Danish Medicines Agency, must comply with the requirements of the Danish Act on Research Ethics Review of Health Research Projects. These requirements are summarised on the National Committee on Health Research Ethics' website in a list (in Danish) of requirements for content. The requirements for any approval by the Danish Medicines Agency are stated in the "Guidelines for applying for permission for clinical trials of medicinal products in humans" and the "Guidelines for applying for authorisation for clinical testing of medical devices" (in Danish).

In addition, the project description must include the scientific description containing the following items:

- Who is participating in the project and which functions and responsibilities have been assigned to the various participating persons/parties.
- Who is the sponsor 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.
- Information about the collection, registration, storage and sharing/transfer of data during and after the project [1] and the 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 of the *Standards for Responsible Conduct of Research at Health*).
- 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 external partners outside AU participate in the project, the arm's length principle and impartiality are crucial, and it must not be possible to cast doubt on the independence, reliability and objectivity of the researcher and the research. Aarhus University's basic principles for responsible conduct of research and research freedom in regard to collaboration with external parties must be followed (see Chapter 4).

A collaboration agreement between the partners involved must always be drawn up in which all parties

[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.

concur with Aarhus University's policy on research integrity, freedom of research and responsible conduct of research. As early as possible in their collaboration, the partners must formally agree on how responsible conduct of research and freedom of research are to be ensured throughout the entire research collaboration. The collaboration agreement must include a description of how the project is to be managed in relation to the items listed above.

The legal aspects of all collaboration agreements must, as far as possible, be approved by the Technology Transfer Office (TTO) at Aarhus University, and be approved and signed by the head of department with which the project is affiliated.

The TTO reviews the legal aspects of the following:

- Publication clauses.
- Collection, registration, storage and sharing/transfer of data during and after he project.
- 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 information about research projects

- The project description and other necessary documents, including agreements, contracts and permits must be completed before a project is begun and agreed. 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 project description, which in most cases will require separate approval by the authorities.
- 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. In connection with clinical trials, errors and discrepancies must be documented in the data management system or on the Case Report Form (CRF) (in Danish).
- 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 either animal experimentation, human subject 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 (in Danish).

1.3 Animal experimentation

- Anyone conducting research on animals must comply with the provisions of the Danish Animal Testing Act (in Danish), and no such experimentation may be initiated without prior approval from the Danish Animal Experiments Inspectorate (in Danish). In accordance with the Danish clinical trials of medical products act (lov om kliniske forsøg med lægemidler), no clinical trials of medical products may carried out on animals without prior authorisation from the Danish Medicines Agency[2]. 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 must 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. Health science research projects and health science data research projects

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. This includes clinical trials of medicinal products in humans and clinical testing of medical devices, as well as projects that utilise sensitive bioinformatic data (dry data), where there may be a risk of significant secondary health findings, including e.g. projects with data from the genome mapping or diagnostic imaging[3].

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 Act on Research Ethics Review of Health Research Projects (in Danish), clinical trial authorisation must be applied for from and granted by the Health Research Ethics Committee in the region in which the principal investigator is employed. There may also be a requirement for notification and approval by the Danish Medicines Agency.

[2] The Act on Clinical Trials of Medicinal Products is expected to replace the Act on Medicinal Products at the end of 20121.
[3] Act no. 1436 of 17/12/2019.

All health science research projects and health science data research projects under 1.4.1. must be submitted to the regional health research ethics committee.

All health science research projects and health science data research projects under 1.4.2. which require approval ethically, but which fall outside the scope of the health research ethics system, may be submitted for approval by the Aarhus University Research Ethics Committee.

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.

Research projects under item 1.4 which are initiated and carried out at Aarhus University must be reported to Aarhus University's internal register of research projects. As a rule, research projects which are initiated and carried out at Aarhus University Hospital or another hospital in the Central Denmark Region must be reported to the Central Denmark Region's internal register of research projects (in Danish).

The management forum for medical health research (in Danish) has prepared Guidelines for cross-institutional collaboration between regions and universities in regard to health data [ed. and General Data Protection Regulations] (Guideline 1) together with the use of patient records (Guideline 2) (in Danish). Here, researchers can find answers to the questions which typically arise when applying for access to relevant health data.

1.4.1. Health science research projects and health science data research projects that must be approved by the regional health research ethics committees [4]

Health science research [5] primarily deals with medical science, pharmaceutical science, nursing science, dentistry, etc., where e.g. biological, clinical, epidemiological, social-medical and psychological research methods are used.

The purpose of health science research is thus to create new knowledge or to test existing knowledge about, for example:

- the emergence of disease or its treatment, diagnosis, prevention, rehabilitation of human beings together with
- human biological, physiological or psychological processes and the genome.

In order for a health science project to require authorisation, the project must have both a health science purpose and one or more interventions[6].

[4] https://www.nvk.dk/forsker/naar-du-anmelder/hvilke-projekter-skal-jeg-anmelde (in Danish)
[5] https://www.nvk.dk/forsker/naar-du-anmelder/hvilke-projekter-skal-jeg-anmelde s. 2 (in Danish)
[6] The Committee for Revision of the Health Research Ethics Committees, Ministry of Health, 2010, proposes in its Recommendation no. 1515 (in Danish), that "the authorization requirement should be limited to health science interventional research. This will make clear that a human subject (or material from such) which is subject to an intervention must be part of the trial requiring authorization, which will in the vast majority of cases be a question of treatment, examination or preventative interventions."

Health science data research[7] deals with the same research areas and same purpose as health science research projects, but here the object of the research is alone the dry bioinformatic data, e.g. there is an absence of intervention.

Both health science research projects and health science data research projects (which have the purpose of creating new knowledge or verifying existing knowledge) must be defined in regard to patient treatment (where the purpose is prevention, diagnosis and treatment etc.) and quality control (where the purpose is to test the function of the clinical unit).

A new act on clinical trials of medicinal products (in Danish) 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 which 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, the *World Health Organization* (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 registered on the *WHO International Clinical Trials Registry Platform (ICTRP)*, or in *ClinicalTrials.gov*. For clinical trials of medicinal products in phase II-IV submitted to the Danish Medicines Agency, these trials are automatically registered in the "EU Clinical Trials Register". Phase I trials and other trials (e.g. involving medical devices, alternative medicine, hypnosis, training etc.) may be registered at *ClinicalTrials.gov.* Help with registration in *ClinicalTrials.gov* can be found at the *Clinical Trial Unit* (in Danish).

All interventional studies involving medicinal products or medical devices under 1.4.1.1 a and 1.4.1.1 b must similarly be registered with the Danish Medicines Agency.

The legal obligation to apply for authorisation from the Danish Medicines Agency applies to all *Conformité Européenne* CE labelled medical devices and CE labelled devices, 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 which addresses all of these points in detail may be prepared.

1.4.1.1.a Interventional studies of medicinal products

[7] https://www.nvk.dk/forsker/naar-du-anmelder/hvilke-projekter-skal-jeg-anmelde p. 3 (in Danish)

This category covers all clinical trials of medicinal products. This refers to investigations 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 rule, clinical trials with medications which are initiated and carried out at Aarhus University Hospital or another hospital in the Central Denmark Region, must be reported to the Central Denmark Region's internal register of research projects (in Danish).

Clinical trials of medicinal products must comply with the Danish *Good Clinical* Practice (GCP) ministerial order. Researchers can contact the GCP Unit at Aalborg and Aarhus University Hospitals (in Danish) for guidance 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 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

This category includes human clinical trials with clinical testing of CE labelled and non-CE labelled 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. Medical devices are devices to examine, monitor, treat or relieve disease in humans.

Clinical investigations involving medical devices must comply with the Danish/European DS/EN ISO 14 155 standard (the equivalent to the International Council for Harmonization's ICH-GCP standard for medical devices). Researchers can contact the GCP Unit at Aalborg and Aarhus University Hospitals (in Danish) for guidance and monitoring of investigations with medical devices that must be authorised by the Danish Medicines Agency.

The development of health apps and software is classified as a medical device, and must therefore 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

This category includes e.g. experiments with testing of dietary supplements, the effect of hypnosis, the effect of training on pain etc.

1.4.1.2. Biological material[8]

This category includes experiments with individually identifiable human biological material.

Biological material is not further delimited in the Danish Act on Research Ethics Review of Health Research Projects, but in practice it covers human tissues, blood, cells, genetic material, skin, nails, hair, eyes and other human organs, faeces, including meconium (the faeces of newborn infants) and human bacteria, as well as human bodily fluids, including saliva, semen, urine samples and the like.

If the biological material is stored in a biobank, then the purpose of the biobank determines the type of biobank in question, e.g. a biobank for a specific research project (research biobank), a biobank for clinical purposes (clinical biobank), etc.

A ***biobank*** is defined as a structured collection of human biological material that is accessible according to certain criteria, and where the information which is bound in the biological material can be attributed to individual subjects. A biobank is regarded as a manual register, as it contains personal data, i.e. individually identifiable data, cf. The Danish Data Protection Agency's guidance on this.

A ***research biobank*** is defined as a structured collection of human biological material, which is stored for a specific health science research project, and which is accessible according to certain criteria, and where information that is bound in the biological material can be attributed to individual subjects.

A research biobank is created when material must be stored longer than the time it takes to collect and analyse the samples, which will typically be approx. 5-7 days. Samples which are immediately destroyed after they have been taken and undergone a completed analysis will not be covered by the biobank concept. A research biobank is an integral part of a research project. A research biobank is considered to be created in a project, regardless of whether the biological material is taken as part of the project, or is collected from an existing biobank.

A **clinical biobank** is defined as a structured collection of individually identifiable human biological material, which is collected and stored primarily for clinical purposes, i.e. to prevent disease, for diagnosis, nursing or patient treatment, or the carrying out of medical or healthcare services. It may be that it is anticipated that there will be a need for further studies of the sample in connection with the continued treatment of the patient, or because it can be used for quality assurance procedures or in connection with the education of medical doctors or other healthcare professionals at the place of treatment.

A **biobank for future research** is defined as a structured collection of human biological material, which is stored with a view to future, unspecified research, and which is accessible according to certain criteria, and where information that is bound in the biological material can be attributed to individual subjects.

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

If, in connection with the research project, biological material is taken from the test subject with a view to storage in a research biobank, the researcher – in addition to obtaining *informed consent* to participate in the

[8] https://www.nvk.dk/emner/biobanker/vejledning-om-bio-mat (in Danish)

research project – must ask the test subject for informed consent for the use of biological material for storage in a research biobank.

Such *informed consent* may not include *informed consent* to any subsequent use of the biological material in another research project *(informed consent* for future research). Such broad *informed consent* is not legally valid in accordance with the Danish Act on Research Ethics Review of Health Research Projects, as the *informed consent* is not related to and based on information about a specific research project.

If the material is from a clinical biobank, the tissue utilisation register (Vævsanvendelsesregisteret) must be consulted to ensure that the human subject has not registered a decision that their biological material may not be used for research.

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. However, persons under relevant education, e.g. medical students, may also take e.g. blood samples under medical supervision. 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.

1.4.1.3 Sensitive bioinformatic data

This category includes research projects involving experiments with the use of sensitive bioinformatic data in which there may be a risk of significant secondary health findings. The concept includes research into genome data or image diagnostic data[9] that is generated in previous research projects or in connection with clinical diagnostics of patients.

1.4.2. Health science research projects and health science data research projects that do not require approval by the regional health research ethics committees[10]

Health science research projects and health science data research projects under 1.4.2. that do not require submission to the regional health research ethics committee must be submitted to either Aarhus University's or the Central Denmark Region's register (in Danish) of research projects.[11]. 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. Health science interviews and questionnaire surveys

[9] https://www.nvk.dk/forsker/forskertjeklister/forskning-i-sensitive-bioinformatiske-sundhedsdata/eksempler-paa-undersoegelser-af-billeddiagnostiske-data (in Danish)
[10] https://www.nvk.dk/forsker/naar-du-anmelder/hvilke-projekter-skal-jeg-anmelde (in Danish)
[11] See page 5

Health science interviews and questionnaire surveys are defined as projects that do not include human biological material, and which have the aim of obtaining knowledge from or about the individuals surveyed within the research project's area.

1.4.2.2. Register-based research projects (data from registries/databases)

Register-based research projects are defined as projects that do not include human biological material, but are based on pure data, i.e. letters, numbers, characters, etc. from existing registers and databases, unless the project is a health data science research project with sensitive bioinformatic data, cf. 1.4.1.3

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

1.4.2.3. Anonymous human biological materials

This category covers material that is collected in research projects in accordance with the legislation at the place of collection, and which is not directly or indirectly attributable to specific individuals[12] (although research projects on assisted reproduction in connection with treatment, diagnostics and research, etc. are excepted, and must therefore be submitted).

1.4.2.3.1 Cell lines:

Experiments on cell lines or similar that come from an approved trial with the collection of cells or tissues, and which have received the necessary approval, do not require submission, unless the experiment concerns the use of fertilised eggs, stem cells and stem cell lines from here, in which case it must be reported[13].

1.4.2.4 Non-interventional studies involving medicinal products

Non-interventional studies are studies in which the medicinal product or medicinal products are prescribed as normal in accordance with the conditions in the marketing authorisation. The decision to prescribe the medication in question is clearly separated from the decision to include the patient in the study, even though the treatment itself does not take place in accordance with an experimental protocol but follows ordinary practice. No additional diagnostic or control procedures are performed, and epidemiological methods must be used to analyse the collected data.[14]

1.4.2.5. Data from patient records

This category includes research projects that use historical data from patient records. Access to historical data in patient records must be approved by the relevant region (in Danish).

[12] https://www.nvk.dk/emner/biobanker/vejledning-om-bio-mat (in Danish)
[13] Cf. Section 25 & 27, 2 of the Act on assisted reproduction in connection with treatment, diagnosis and research, etc.
[14] https://www.retsinformation.dk/api/pdf/152402 (in Danish)

2. Data

Scientific data is to be collected and stored in accordance with current statutory rules and other provisions. Data is 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:

- Information about the collection, registration, storage and sharing/transfer of data during and after he project[15] and the responsibility for the data processes described must be stated 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 project, except where this conflicts with other legislation or professional standards, cf. AU's policy section 3.2 and AU's Instructions for the storage and management of research data.
- There must be open access to material on which publications are based (FAIR principles), except where this conflicts with legislation or contractual obligations, cf. AU's policy section 3.2 and AU's Instructions for the storage and management of research data.
- 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 (in Danish).

- 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 pseudomise[16] data whenever possible in the given context. The security requirements for pseudonymised data are less strict.
- In accordance with the data protection legislation (in Danish), 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 met. 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, which stipulates a storage period of 5 years. [17]

[15] See note 1.

[16] Pseudonymising is when there is a key which may be attributed to a person. Pseudomised data still falls under the scope of the Data Protection legislation.

[17] Once the EU regulation on clinical trials comes into force, it will include a requirement for 25 year's storage.

- 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 deleted, 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 the Data Protection Unit 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 (in Danish) and other supplementary legislation must be complied with. See also AU´s Instructions for the storage and management of research data.

3. Publication and authorship

Researchers at Health must follow AU's basic principles and disclose all relevant relationships in the final publication or research communication, so that it is clear that the central principles have been complied with. As a minimum, the following must be stated:

- potential conflicts of interest
- funding
- authorship
- quality assurance (peer review)
- the nature of any external party's contribution.

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. If it is necessary so as to be able to safeguard the external party's intellectual property rights, time may be allocated to ensure that the external party has the option of postponing the planned publication for an appropriate period of time. Such postponements will typically last for three to four months, and may never exceed six months, from the date of receipt to submission of comments. (See AU's basic principles). In the case of clinical trials, the *University Hospital's guidelines for entering into research* (in Danish) contracts must be followed, in which the postponement must never exceed 3 months.

- 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.

In order to be able to obtain authorship for the scientific publication, the following minimum contribution

must have been made:

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.

In addition, all authors must approve the final manuscript, which is submitted for peer review, as well as the final published version of the manuscript. Aarhus University expects anyone who acknowledges 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's policy for research integrity, freedom of research and responsible conduct of research.

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.
- 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 translation, may not take place. On the other hand, secondary publication (e.g. an English language article subsequently published in Danish (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.
- The rules outlined above must also be complied with in connection with publication through other channels than journals.

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

Conflicts of interest are situations in which researchers have financial or other interests that may compromise or influence their research findings. What is decisive in this regard is not whether the research is actually

influenced by the conflict of interest, but that there are grounds for suspicion, well-founded or not, that it may have been, cf. the Basic principles for responsible conduct of research and research freedom in regard to collaboration with external parties. 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 proof-readers 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 external partners

At the Faculty of Health, Aarhus University's basic principles and core principles are followed, including specific requirements for the handling of research collaboration with external parties. This must ensure that it is not possible to cast doubt on the independence, reliability and objectivity of the researcher and the research. In this context, external parties refers to legal entities other than Aarhus University.

These basic principles do not apply to national and international research collaboration with other universities unless funding is received for the collaboration or a party has rights to the results of the collaboration. In this context, results are defined as intellectual property rights/Intellectual Property.

4.1 Types of collaboration

As a researcher you may become involved in many different types of collaboration. Based on the character, contents and conditions for the collaboration, these can be categorised under four types: Researchers and research teams at Aarhus University can see examples of the different types of collaboration and get help with specific handling of the different types of research collaborations with external parties by clicking on the type of collaboration.

1. **Co-financed research:** A collaboration between a university and at least one external party. The parties define the scope of the collaborative project together, and both contribute to carrying it out. Generally speaking, results generated wholly or in part by AU researchers belong to the university, and publication must be possible. The university co-funds the project (financially or by contributing manhours).
2. **Commissioned research:** The university may perform commissioned research projects or services for an external party. All of the university's costs must be borne by the external party. Ownership of results and publication rights must be defined in the collaboration agreement.
3. **Unconditional grants, donations and deeds of gift:** A financial contribution to support research is made to a researcher or to the university. All conditions must be clearly described. In case of unconditional grants (aside from standard requirements for reporting, bookkeeping, information on changes, etc.), the notice of award will normally be considered sufficient as a written agreement. If

the grant giver attaches special conditions to the grant, the collaboration is then classified as co-financed research or commissioned research.

4. **Research-based public sector consultancy:** This is an umbrella term for a variety of research services the university performs for the government, the municipalities and companies. Framework agreements are entered into between the universities and the respective ministries. Research results must be made accessible to the public.

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.

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

The TTO can provide more information, advice and guidance.

4.2 Regulatory requirements in regard to collaboration with companies

The Danish Health Act lays down so-called 'association rules', that require public sector healthcare professionals 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 is 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.

Appendix 1. Overview of agencies who approve health science research projects and health science data research projects

Overview of the approval process for studies with data

	The Danish Medicines Agency	Health Research Ethics Committee (REC)	Research Ethics Committee at AU (in cases in which the project falls outside the REC system)	Region	Data supplier	AU's register or CDM's register[18]	The Danish Data Protection Agency
Health science research projects and health science data research projects that require approval by the Health Research Ethics Committee							
Interventional studies with medicinal products	X	X				X	
Interventional studies with medical devices	X *	X				X	
Other interventional studies		X				X	
Sensitive bioinformatics data		X				X	
Health science research projects and health science data research projects that do not require approval by the Health Research Ethics Committee							
Observational studies as well as interviews and questionnaires			x			x	
Register-based research, data from national databases and/or registers					x	x	
Non-interventional studies of medicinal products						x	
Data from patient records				x		x	
Research projects where the Danish Data Protection Agency must be notified							
Where there is also processing outside the territorial scope of the GDPR							x
Where publication in a recognised journal or similar – and data is not anonymous							x

* Non-CE labelled equipment or CE labelled equipment used for other purposes

Overview of approval of trials where biological material is included

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 for 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 for 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
3) Anonymous biological material	• No registration requirements	• No registration requirements