

# Guidelines for research-related contracts

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NOTE: This is a translation of the Swedish version (*Riktlinjer för forskningsrelaterade avtal*). In the event of any discrepancy between the versions, the Swedish version constitutes the official decision, and the Swedish wording will prevail.



**Karolinska  
Institutet**



## **Guidelines for research-related contracts**

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## 1 Introduction

Karolinska Institute's (KI) mission is to conduct education and research. In addition, KI shall also contribute to society by engaging in collaborations, spreading knowledge and information about its activities and ensuring that research results are implemented to the benefit of society<sup>1</sup> (the so-called "third mission").

The framework of KI outreach activities is set by the applicable legislation and internal steering documents. KI's scope for action and freedom to contract is therefore limited.

A written agreement on the rights and obligations agreed upon between parties makes clear the expectations and requirements of each Party, thereby reducing the risk of costly disputes.

These guidelines are based on applicable laws and regulations and recommendations issued by the Association of Swedish Higher Education Institutions (SUHF).

## 2 Purpose and scope

The purpose of these guidelines is to explain KI's scope for negotiation and indicate the risks that must be considered and that should be avoided in contracts signed by KI. The guidelines are addressed to all KI staff.

## 3 General principles

It is important to make clear which rules apply to the planned study or research project at an early stage of the process. Assistance in this can be provided by professional support services with the special competence and knowledge<sup>2</sup>. As part of this professional support service, a legal counsel can provide relevant documentation and contract templates.

For the purposes of advising on and reviewing an agreement, the contract lawyer needs to receive a detailed description of the planned activity. Resolving regulatory issues at an early stage of the process often speeds up the contract process.

Contracts are required:

1. when demanded by the regulations,
2. for commissioned research,
3. for cash receipts or payments,

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<sup>1</sup> Chapter 1 section 2 of the Higher Education Act (1992:1434).

<sup>2</sup> KI's professional support services encompass functions and processes at all levels of the organization, including HR, finance, communications, education, student support, researcher support, facilities, security, IT, legal, archive/registry and management support.

4. for research collaborations,
5. for long-term access to premises or participation in an activity by a person who is neither a member of staff nor an enrolled student at KI,<sup>3</sup> and
6. the receipt or provision of material such as data, personal data, samples, animal models, equipment etc.<sup>4</sup>

KI may only enter a contract if:

1. it is in line with applicable rules,
2. it is necessary for the fulfilment of the mission of KI,
3. the terms and conditions sufficiently clarify the rights and obligations of each party,
4. the terms and conditions promote responsible management of state resources of public funds,
5. the parties can be expected to meet their undertakings,
6. risks have been analysed and minimised to an appropriate level, and
7. it is done in writing.

## 4 Responsible administrator

In order to process a contract, the relevant KI department must appoint a responsible contract administrator<sup>5</sup> as soon as the planned collaboration starts to take shape. The responsible administrator must be employed at KI, be unbiased and have no conflict of interest.

The roles of the responsible administrator include, but are not limited to:

1. ensuring that those responsible for the department in question (e.g. Head of Department and departmental administrative manager) approve the scientific and financial terms of the contract,
2. ensuring that the necessary authorisations and approvals have been obtained,
3. coordinating contacts with the counterparty,
4. handling communication with the legal counsel/legal unit,
5. ensuring that all issues identified are looked into by the right professional support service (e.g. the Grants Office, HR Office, Procurement Unit, International Relations Unit, the Executive and Professional Education Unit, the Development Office, the Information Security Office), and
6. have a good knowledge of the contents of this steering document, the *Rules governing Conflict of Interest at Karolinska Institutet* and the *Guidelines on intellectual property and corporate collaborations*.

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<sup>3</sup> The Association of Swedish Higher Education Institutions (SUHF), *Rekommendationer avseende personer som vistas i lärosätets lokaler och deltar i verksamhet vid lärosätet men som varken är antagna till studier eller anställda vid lärosätet* (REK 2013:3), 2013.

<sup>4</sup> Agreements are not required for the disclosure of data or information in accordance with the principle of public access to information.

<sup>5</sup> Responsible administrator is not a job title, it refers to the person responsible for pushing the contract through the process.

## 5 Legal counsel

The legal counsels at the Legal Unit can provide advice on the terms and conditions of collaborations, and assistance with the review and interpretation of contracts. The legal counsels have access to specially drawn-up contract templates, forms and supplementary information material that might facilitate project planning and contract drafting.

Executive managers (Heads of Department and Administration Heads) at the department are responsible for deciding which contracts need to be reviewed by the Legal Unit.

When advising on and reviewing contracts, the legal counsel provides recommendations.

The legal counsel does not represent KI in contract negotiations with the counterparty other than in exceptional cases and when agreed by the legal counsel.

It is important that the legal counsel receives the documentation that he/she deems necessary for the purposes of advice or review.

### 5.1 Processing time

The amount of time to put in place a signed contract can vary considerably depending upon several factors. It is often an advantage if KI templates are presented to the counterparty since many contractual terms and conditions are governed by Swedish law and deemed essential in advance.

The type of contract also affects the processing time.

Some contractual terms are negotiable, and this also affects the processing time, as it necessarily entails communication with the counterparty.

### 5.2 Priority processing

Cases are processed in order from the date of submission to the Legal Unit. In exceptional circumstances, such as if KI might suffer financial damage if an agreement is not signed by a certain date, one case may be given priority over others.

A decision on such special circumstances is made by the head of the Legal Office after consultation with the executive group of the department involved (i.e. Head of Department or equivalent).

## 6 Advice and templates

Legal review of draft contracts, questions regarding contracts or suitable contract templates can be sent to the Legal Office, [avtal@ki.se](mailto:avtal@ki.se).

This mailbox is for internal use by KI-employees only.

## 7 Legal review of draft contracts

For a draft to be reviewed, a clear description of the background and the intended arrangement (e.g. a project description and an account of a possible use of personal data or material) must be provided. If the contract involves a financial contribution in the form of a grant, the application and terms and conditions of the grant must be provided together with the draft. Before the legal review can commence, the issues listed on p.4 as well as any relevant procurement must be dealt with.

The legal counsel may request complementary information or request adoption of further measures.

### 7.1 Scope of review

The legal counsel makes recommendations based on mandatory laws and rules and customary risk management. It is not possible for the legal counsel to examine all aspects regulated in a contract. The relevant department must therefore ensure that the following issues are examined:

1. financial conditions and budget,
2. scientific aspects,
3. necessary permits and consents,
4. procurement,
5. confidentiality, and
6. insurance coverage.<sup>6</sup>

### 7.2 Deviation from recommendation

Contracts are reviewed from a general, overall perspective in the interests of lawfulness and to achieve a balance in the parties' rights and obligations.

The recommendations of the legal counsels have been made after careful consideration and should therefore be followed. If the relevant department opts to depart from the recommendations of the legal counsel the authorised signatory must be informed prior to signing.

## 8 Negotiation process

The parties will negotiate the content of a contract until they reach a definitive version. The responsible administrator has a central role in coordinating the contact between KI and the counterparty as well as internally between different KI professional support services.

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<sup>6</sup> Examination of insurance coverage means assessing whether the intended activity is covered by KI's insurance policies or whether additional policies must be taken out through the Legal, Financial and Administrative Services Agency.

Before a draft contract is sent for legal review, the Head of Department or the equivalent is to ensure that KI can meet the proposed contractual terms and conditions (e.g. that the research plan and budget have been approved).

The draft is then sent to the Legal Unit as described in section 7.

Once the legal counsel has made his/her recommendations, the relevant persons at the department are to decide on the revised draft, its tracked changes, and comments. The draft is then sent to the counterparty with the comments intended for the counterparty and without the comments only intended for KI's internal discussion. It is important that the responsible administrator makes sure that all internal comments made by the legal counsel are deleted before the contract is sent to the counterparty for review.

All amendments and comments to be shared with the counterparty must be visible (tracked) to facilitate the negotiation process.

If the counterparty accepts all amendments the agreement is deemed fully negotiated and a clean final version is produced for signing.

If, however, the counterparty has objections to the proposed amendments or introduces new terms/conditions, the review process must continue. It is common for drafts to be sent back and forth in this way several times before the wording of an agreement is finally agreed.

## 9 Final version

Once the negotiation is completed, a clean final version of the contract needs to be produced, at which point the responsible administrator must examine the document to make sure that all the necessary changes have been made and that the contract is ready in all other respects for signing. The final version should be saved as a non-editable PDF file to prevent any additional amendments being made prior to signing.

## 10 Signing

Contracts may only be signed by a designated authorised signatory in accordance with the *Decision-making procedures and delegation rules for Karolinska Institutet* or a special delegation decision (e.g. by a Head of Department either alone or in conjunction with another official, such as the University Director or head of the Grants Office). Contracts on behalf of KI may not be signed solely by an individual employee, such as a principal investigator or research group leader.

In a legal sense, a contract is reached once one party accepts a counterparty's offer. This can be done in several ways, most commonly that the parties sign by hand a physical copy of the agreement, which is the method currently recommended for contracts with KI. Other acceptable methods are described below.



If the parties cannot meet for simultaneous signing, the signatures can be collected by sending copies of the contract to each other so that each party ends up with a fully signed copy. Such an exchange of copies of the contract can be achieved either by regular mail or by sending signed copies as scanned PDF files by email.

The responsible administrator must ensure that the signatures of the authorised signatories are always dated, since a contract can become effective on the date of its signature.

### **10.1 Electronic signatures**

A digital (electronic) signature is defined as data in electronic form which is used to verify the content and integrity of a document and the identity of the sender.

KI uses different solutions for the electronic signature of documents.

Electronic signatures are permitted if the technique is considered to be reliable by the relevant department.

Scanned signatures pasted in as image files are not acceptable as they are simple to forge.

### **10.2 Contracts reached by accepting terms and conditions**

Some organisations such as research grant entities often present a list of terms and conditions that the beneficiary of the grant may choose to accept by, for instance, logging on to a digital service and checking various boxes. In such cases the authorised official shall accept the terms and conditions and keep an appropriate record.

This is common when researchers apply for research grants and the financier has non-negotiable terms and conditions that apply to the awarded grant.

## **11 Researcher consent**

At KI, academic staff enjoy the “teacher’s exemption” or “professor’s privilege”, which, in simple terms means that the researchers generally own the results of their work.<sup>7</sup>

When research agreements contain conditions on confidentiality or the allocation of intellectual property rights (IP), each participating researcher, as a rights holder, must testify that he/she approves the sharing of the rights as per the agreement. This is done by signing a *researcher consent* form in which the researcher certifies that he/she has read, understood, and approved the content of the contract. In signing the form, the researcher also acknowledges that he/she is aware of his/her confidentiality undertaking vis-à-vis the counterparty.

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<sup>7</sup> See *Guidelines on intellectual property and corporate collaborations*

The researcher consent form must be signed by all participating researchers once the authorised official at KI has signed the agreement. Researchers who join the project at a later date must always sign their consent form before commencing their work in the research project.

It is the responsibility of the principal investigator (PI) to gather all the consent forms. The responsible administrator shall inform the PI and the authorised official of these requirements.

Signed consent forms are internal documents and are not to be sent to the counterparty.

## **12 Registration**

Once a contract has been signed, the responsible administrator is to ensure that it is duly registered along with all signed consent forms (if any).

## **13 Prohibited terms**

The creation of a contract or the content of a contract may not contravene the prevailing legislation or internal steering documents. It would be impossible to give an exhaustive list of all such situations, but the following are some examples.

Only when especially justified and lawful, departures may be made from some of the following rules and only after consultation with a legal counsel.

### **13.1 Concealment of information**

The principle of public access to information and the individuals' right to access public documents applies to KI and is only limited by law.<sup>8</sup> Contracts with confidentiality terms and conditions must therefore allow the disclosure of information by KI when KI is required to do so by law, by court, etc.

### **13.2 Deleting or returning information**

KI is required to archive public documents.<sup>9</sup> Contractual terms and conditions stating that the received documents and information shall be deleted, destroyed, returned or the like may only be accepted if they are limited by KI's right to retain copies when so required by the applicable rules.

### **13.3 Terms and conditions contravening principles of academic research**

KI is subject to the Higher Education Act and its general principles for research.<sup>10</sup> The following general principles shall apply to research at all Swedish higher education institutions:

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<sup>8</sup> Public Access to Information and Secrecy Act (2009:400)

<sup>9</sup> Archives Act (1990:782)

<sup>10</sup> Chap 1 section 6 of the Higher Education Act (1992:1434)

1. research issues may be freely selected,
2. research methodologies may be freely developed, and
3. research results may be freely published.

Research contracts may not contravene these general principles. Terms and conditions giving the counterparty the right to prevent the publication of research results or that hinder KI from conducting future research on the results generated are not permitted. Publication may only be delayed for a limited time when necessary for making a patent application.<sup>11</sup> KI shall always retain a research licence bestowing the right to use its research results for the purposes of further research and educational use.

### **13.4 Warranties and representations regarding research results**

Research contracts may not contain any warranties concerning research results, such as the commercial usefulness or fitness for purpose of results or that they will not infringe the proprietary rights of a third party.<sup>12</sup>

### **13.5 Processing of personal data**

The rules regarding the processing of personal data<sup>13</sup> require the signature of certain types of contracts. When a party processes personal data on behalf of another party, a Personal Data Processing Agreement must be signed. When transferring personal data, KI must sign another contract in accordance with GDPR.

### **13.6 Grants and commissioned research**

Financing that is provided gratuitously and without expecting specific results or outcomes in return from KI is a grant. The opposite of a grant is commissioned research. Guidelines have been drawn up by the Swedish National Financial Management Authority (ESV) to help in the determination of which of these two forms the financing takes.<sup>14</sup> Commissioned research entails, for example, commercial terms and requirements on performance or outcomes and the external financier's rights to the results.

It is not required that a grant fully covers all the costs of a project; a grant can therefore partially finance a project.

In the case of commissioned research, on the other hand, KI must receive payment in accordance with the principle of full cost-coverage.<sup>15</sup> The financier shall be invoiced the total cost of all work completed, calculated according to internally established models, inclusive of VAT when applicable.

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<sup>11</sup> Normally for up to 90 days. See *Guidelines on intellectual property and corporate collaborations*

<sup>12</sup> SUHF, *Analys avseende villkor för externfinansierad forskning* (REK 2016:3), 2016, p. 10.

<sup>13</sup> e.g. GDPR (EU) 2016/679 and the Act containing supplementary provisions to the GDPR (2018:218).

<sup>14</sup> National Financial Management Authority, *Erhållna bidrag och donationer* (ESV 2005:14), 2005, p. 4.

<sup>15</sup> Annex 4 on fee-financed activities in the government's appropriation directions for higher education institutions.

### 13.7 The right to accept payments

Further to the specific authorisations in the government's directives, fees may only be charged for:

- journals and other publications
- information and course material
- conferences and courses
- advisory and other such services
- premises
- equipment
- contracted courses
- executive and professional education
- commissioned research

An example of advice and other similar services is when staff from KI are engaged as speakers at a conference or lecturers on a course. The term can also refer to a contract involving KI processing and compiling information.<sup>16</sup> The provision of services provision against payment of a fee on this basis may never concern research, even if its execution can have certain academic benefits.<sup>17</sup>

KI may not engage in a contract and receive payment for the manufacture of material or other physical goods intended to be supplied or transferred to a client.<sup>18</sup>

### 13.8 Purchase of goods and services

Agreements concerning the purchase of goods and services must comply with procurement rules.<sup>19</sup>

### 13.9 Illicit trade of goods and services

Barter trade is the exchange of goods or services between two parties without the exchange of money.<sup>20</sup>

If a company gives KI access to research material or equipment in exchange for research results, this amounts to commissioned research in exchange for goods which have not been properly procured. This is only permissible if KI receives full payment for all its work completed.

## 14 Minimising risk

KI is obliged to take reasonable measures to limit risk and prevent damages or losses.<sup>21</sup> Below are some examples of how this can be done.

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<sup>16</sup> ESV, *Att ta betalt med avgiftsförordningen* (ESV 2015:45), 2015, p. 21

<sup>17</sup> SUHF, *Analys avseende villkor för externfinansierad forskning* (REK 2016:3), 2016, p. 6

<sup>18</sup> *Guidelines on intellectual property and corporate collaborations*

<sup>19</sup> Public Procurement Act (2016:1145)

<sup>20</sup> *Sponsring som finansieringskälla – En vägledning för statliga myndigheter*, ESV 2002:15

<sup>21</sup> Ordinance on risk management at public authorities (1995:1300)

### **14.1 Indirect damages**

Agreements shall include terms and conditions that limit KI's liability in a reasonable and appropriate manner. Liability shall always, as far as is legally possible, exclude indirect damages and be limited to direct damages only.

### **14.2 Limitation of liability**

The Parties can choose to limit liability resulting from breach of contract by capping the amount payable in damages (a liability cap)). The department concerned must then consider what risks the agreement entails and whether they are acceptable.

### **14.3 Insufficient insurance coverage**

It is necessary to ensure that KI has sufficient insurance coverage for the activities covered by the contract.

### **14.4 Choice of law**

A choice-of-law clause is a term of a contract that specifies which law will be applied to interpret the contract in the event of a dispute. The choice of Swedish law as the applicable law to the contract is the best option for KI. The choice of other national laws should only be accepted after consultation with a legal counsel.

KI should provide for Swedish law to apply, and for the courts of Sweden to have jurisdiction in the event of a dispute in the following contracts:<sup>22</sup>

1. agreements on research primarily conducted at and independently by KI (e.g. commissioned research)
2. material transfer agreements (MTA) with KI as provider
3. Persona Data Processing Agreements for where KI is the personal data controller.

### **14.5 Dispute settlement**

The dispute settlement clause states when and how a dispute is to be settled. Swedish courts, with the Stockholm District Court as the court of first instance, are to be preferred.

The choice of law should always correspond with the choice of dispute settlement, in that the law of choice is to be applied by the courts of that same country.

Arbitration can be more expensive than litigation in court and should therefore be avoided. This applies even though companies usually prefer arbitration. Litigation in court in a foreign country can hamper KI's ability to defend its rights and it can be costly to hire local attorney.

The legal counsels provide advice and support regarding these clauses.

### **14.6 Counterparty**

Knowledge of the counterparty is also part of risk minimisation. An overall check of the counterparty is recommended before entering contract negotiations.

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<sup>22</sup> See section 14.5 for more on settling disputes.

### **14.7 Contracts with retroactive effect**

Contracts are to be fully negotiated and signed before the collaboration may commence. Signing a contract retroactively (i.e. so that is effective from an earlier date) increases the risk that the parties will have different understandings of what has been agreed and that any deficiencies will not be subsequently rectifiable. If the work is subject to regulatory requirements for handling samples or personal data, for example, absence of a contract could render the performed work illegal. Unresolved issues can have a significant effect on the ongoing research project and lead to complex and costly disputes.

### **14.8 Contract follow-up and deficiencies**

The department responsible for the activities to which the agreement applies (e.g. the Head of Department and departmental head of administration) shall ensure that the contract is complied with and take measures if deficiencies are detected on following up the activity in question or in any other instances.

### **14.9 Affiliates**

Apart from employees, certain people are engaged in KI's activities as *affiliates*.<sup>23</sup> From a contract perspective, it is essential that the relevant department acts in the knowledge that an affiliate is employed elsewhere and is therefore generally to be considered a third party in contractual relationships between KI and another party, such as, for example, a company. If an affiliate is to take part in the agreed activity, the counterparty should be informed early on of this and the affiliate's status so that appropriate solutions can be negotiated.

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<sup>23</sup> *Affiliation rules and instructions*