

Guidelines on intellectual property and corporate collaborations

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The Swedish version has preferential right of interpretation.



**Karolinska
Institutet**



Guidelines on intellectual property and corporate collaborations

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1. Introduction

It is vitally important for Karolinska Institutet (KI) that the scientific findings generated by its researchers are put to public benefit through either corporate collaborations or commercialisation by the researchers' own company or through licencing to a third party. In addition to research and education, KI's mission is to interact with the surrounding society. Much of this interaction takes place in the business sector. For KI this entails the commercialisation and utilisation of intellectual property (IP) in order to develop new therapeutic methods and products of benefit to patients.

Intellectual creativity, idea-sharing and transparency are the core values of an academic environment. Since intellectual property is a natural outcome of the work performed in this environment, every effort must be taken to ensure that the interests of KI and its employees do not compromise the principles of open access and knowledge sharing.

2. Aim

These guidelines have been written to clarify how intellectual property, material and resources produced through research and education at KI are to be handled in accordance with prevailing regulations and practice, and the rules that apply to the utilisation of these assets.

The guidelines also align with the 2008 EU Commission recommendation on the management of intellectual property in knowledge transfer activities and Code of Practice for universities and other public research organisations.

3. Scope

The guidelines apply to all KI employees unless otherwise stated.

4. Intellectual property created at KI

4.1 Definition of intellectual property

IP is defined in these guidelines as such intellectual property that, according to applicable law, has or may have legal protection, such as patent, copyright, trademark and design protection, and whatever constitutes the product of intellectual work, such as inventions, knowledge, methods, texts, compilations, information, calculations, computations and drawings.

4.2 Ownership right

The general principle is that the ownership rights to IP created within research and education at KI shall vest in the creator.^{1 2}

¹ Whoever has created a literary or artistic work is considered its creator and consequently owns the copyright to the work (see the Act on Copyright in Literary and Artistic works (SFS 1960:729) and the Patents Act (SFS 1967:837).

² In accordance with the 'professors' privilege'; cf. the Act on the Right to Inventions by Employees (SFS 1949:345) and the customary practice at Swedish universities.

The creator can be either an employee or a student at the university. An extended right to patentable inventions, relative to that which otherwise generally applies to employees in the workplace, is afforded to teachers (i.e. all teachers and researchers covered by KI's appointment procedure for teachers and admitted doctoral students). This is a consequence of the "Professor's privilege" and the broader interpretation of teachers' rights to cover more than just patentable inventions that is customary at KI. KI shall, however, have the right of use to IP owned by the researchers for the purposes of research and teaching activities.

Since students are not employed at KI, the university has no claims on their IP.

4.3 Teaching material

A teacher who produces teaching material as part of his/her work as a KI employee is considered the author of such material. KI has, however, the right to use such material, which means that KI may use the material in its normal activities and for the teaching purposes that were foreseeable at its creation, and that KI may amend or update the material as necessary. The right of use also includes a right to produce, make available and store printed and digital copies of the material. KI's right does not limit the author's copyright to the teaching material, which means, amongst other things, that the teacher is free to use it for purposes such as the production of textbooks, articles or other scientific works and when teaching for another organisation.

4.4 Software

A teacher who produces software as part of his/her work at KI is considered the creator of such software and has full right of disposal over it. KI has, however, the right to use such material produced in the course of his/her employment.

Regarding software produced on behalf of KI by external consultants, contracts shall be drawn up regulating rights of ownership and use pertaining to that software.

Software produced by external consultants and paid for by KI may be commercialised by teachers (as defined above in 4.2) on condition that KI is fully compensated for costs defrayed in accordance with the principle of full cost recovery.

If the final product also contains patient data or other data subject to special requirements (e.g. ethical or regulatory), such requirements must, of course, be fulfilled. Some patient data is owned by Stockholm County Council, in which case the Stockholm County Council's own regulations apply.

4.5 Third-party IP rights

KI employees shall respect third-party IP rights (i.e. may not violate another person's or organisation's IP rights).

4.6 Conflicts

Conflicts about rights to academic works and the interpretation of contractual principles as described in these guidelines shall be settled in the first instance via mediation or other informal process overseen by the departments involved.

4.7 Publication

It is incumbent upon the researcher to ensure that his or her research is published or otherwise made available to the public, and to do so in compliance with any confidentiality requirements or contractual undertakings.

A researcher who intends to apply for a patent or design protection for his or her IP is urged to consider refraining from publication or other such public dissemination of said IP until the patent- or design application has been filed.

Sometimes the publication interests of the research and the researcher collide with the commercial interests of the financing company (e.g. the so-called novelty requirement, whereby only inventions that are ðnewö before the patent application is filed may obtain patent protection). Even if the rights to the results are transferred, the researcher has a legitimate interest to publish within a reasonable time without being hindered to do so by any future patent application by the rights-holder. Contracts shall therefore include provisions concerning publication delays and the maximum time within which the researcher is not allowed to publish his or her results. A maximum publication delay of up to 90 days is standard.

5. Principles of collaborative and contract research

Collaboration can take many forms and, depending on its nature, be subject to different KI rules and guidelines.

A researcher's IP rights might be affected in some instances of collaborative and contract research. In both cases, the counterparty can be assigned a right of ownership or right to use that affects the researcher's and KI's IP rights.

Research collaborations may take place with other parties under the following conditions:

- The collaboration must be consistent with KI's overarching mission as a university in the field of medicine and health.
- The collaboration must maintain a high standard and respect the principles of transparency and clarity.
- The collaboration must comply with applicable laws, guidelines and ethical principles in force at KI.
- No contract or grant may be accepted if it risks damaging public trust in KI.
- The collaboration must allow KI researchers and students to publish their research findings.
- A condition of all contracts is that KI and its researchers may continue to conduct research in the field. A minimum requirement is that KI has the right to use the results, without claims for compensation, for the

purposes of further research and education (õresearch licenceõ), regardless of how any contractual IP transfer is affected.

- The creator shall own the IP that he or she generates, with the possible exception of contract research.
- The transfer or licensing of IP owned by a creator at KI is subject to separate agreement and upon market compensation.
- A written contract shall be drawn up between both parties prior to the collaboration.
- All researchers involved in the collaboration are required to give their consent to the content of the contract by signing separate consent forms with KI, which are to be collected by the principle investigator.

5.1 Collaborative research

Collaborative research is research that is conducted with academic organisations, companies, foundations or other institutes and in which all parties are actively involved and either share the costs or contribute other resources.

A contract must be drawn up to regulate such collaboration and, importantly, the ownership rights to related IP.

Research collaborations are to be well defined and delineated to prevent that ownership of IP, over and above what has been agreed and is not included in the project, is transferred unintentionally. IP rights are regulated differently depending on the nature of the collaboration. The right to background IP shall be regulated before the collaboration commences. As a general rule, the IP resulting from collaborative research belongs to the one who has created it. IP rights for anyone other than the creator are conditional on full cost-recovery. If a collaboration means that IP ownership is transferred or its use licensed to a partner, compensation shall be paid to the creator corresponding to the market value of the IP utilisation.

5.2 Contract research

Contract research is research in which a specific project is formulated and fully financed by the commissioning entity (i.e. full cost-recovery). A project cost estimate including costs for personnel, premises, material, equipment and other (overhead or INDI) shall be drawn up to ensure full cost recovery.

5.3 Collaboration with companies or other organisations in which employees have a personal interest

KI sometimes has reason to collaborate with a company or organisation that is wholly or partly owned by an employee, or in which the employee has a personal interest.

In such cases, in order to maintain public trust in KI, the employee who has an interest in a company or organisation such as shares, employment or board membership, in addition to the rules that apply as per the above to all KIø

collaborations with business, including KI's holding company and its subsidiaries, may under no circumstances be involved in the administration of or decisions concerning a matter relating to KI's relationship with the company or organisation. This is necessary to avoid a conflict of interest that would invalidate the agreement or decision. Such matters are to be prepared by the university administration and decided upon by the University Director (see KI's rules for handling of secondary occupations).

In such situations it is also important that the scope and conditions of the project are thoroughly considered in a way that safeguards the independence and impartiality of the individual researchers (including doctoral students) and the research group, and that the rules and guidelines concerning conflicts of interest and secondary occupations are complied with.

University teachers (as defined above in 4.2) have certain extended rights to engage in secondary occupations, so called R&D secondary occupations, and may, alongside their position at KI, be employed, commissioned or engaged in other activities related to research or development within the field in which they are employed at KI on condition that in so doing they do not damage public trust in the university. The secondary occupation must not obstruct the employee's work or compete with the university's commissioned activities, and must be kept entirely separate from the employee's ordinary occupation at KI.

Further, KI's resources or trademarks (including logotype) may not be used for a secondary occupation or other sideline activity. Exceptions can be made if an agreement regarding the limited use of apparatus and equipment is signed between KI and the employee and approved by the University Director or Vice-Chancellor. This is on condition that such an agreement entails no conflict of interest and includes full cost recovery (see also KI's rules for secondary occupations).

As a general rule, it is not allowed to charge a consultancy fee to KI from employees own companies for regular work conducted at KI as part of their employment.

All employees of KI are required to regularly report any secondary occupations to their Head of Department or the equivalent. Teachers are also required, on their own initiative, to report new or altered secondary occupations.

5.4 Participation of students in externally financed projects

Undergraduate and postgraduate students are the primary authors of their theses.

It is possible that projects involving students require separate regulation concerning ownership and confidentiality in respect of a third party. In such cases, the students must be informed of any such regulations affecting the execution of the project and must enter into the necessary agreements before the project commences.

5.5 Executive and professional education

KI provides customized professional education and training to the staff of other organisations. The principle of full cost-recovery applies. It is up to the Head of

Department to ensure that such education does not impinge on the university's state-financed education. Decisions on executive and professional education are taken by the university administration's executive and professional education unit.

5.6 Right to enter into agreements

The authorized signatories to enter into agreements are given in the Vice-Chancellor's decision-making procedures and delegation rules. Heads of Departments have responsibility for all the activities of their department. In some cases, a Head of Department is required by the delegation rules to take decisions with another university post-holder (e.g. the University Director). Researchers may not, of course, enter agreements on behalf of KI unless authorised via delegation.

5.7 The KI trademark

The use of the KI trademark in communication concerning collaborative projects is determined by KI's role in and ability to influence the nature of the collaboration, and by whom the primary sender of the message is. The main principle is that the KI trademark may not be used without KI's written consent. KI's rules for the use of its trademark must always be observed for agreements and contracts.

Thorough rules and guidelines regulating the use of the KI trademark and logotype are given in KI's brand platform and in the university's graphic identity manual. There are also channel-specific instructions for media relations, news articles and social media under "Communication" on the staff portal.

5.8 The principle of public access and confidentiality

When considering agreements with external partners it is important to bear in mind that KI is a public authority. The principle of public access gives the general public and the media the right of access to information about the university's activities, a right that may only be restricted in accordance with the Public Access to Information and Secrecy Act (SFS 2009:400).

There may be legal grounds to keep secret certain data generated by a collaborative project with a private business. However, KI cannot contractually guarantee a counterparty in advance that certain data will be protected by confidentiality. Confidentiality clauses may not be used to the extent that they inhibit the normal exchange of data and information in the research environment.

6. Materials and resources

6.1 Biological and chemical material

Sometimes a collaborative project with an external partner entails the transfer of biological material, such as cells, antibodies, vectors, proteins and animal models, or chemical substances. When KI is in receipt of materials that are associated with restrictions in a third party contract, the material must be handled in accordance with said contract.

Chemical and biological material produced at KI by researchers employed at KI is owned by KI. Material from research projects can, however, be transferred to companies under certain circumstances. A Material Transfer Agreement (MTA) shall be drawn up with the external party. The agreement is to be signed by the Head of Department in accordance with the Vice-Chancellor's decision-making procedures and delegation rules. The material may only be used for non-commercial scientific purposes. The transfer of human tissue in the KI biobank is to comply with applicable biobank legislation. It is important to note that Stockholm County Council is often responsible for patient material and that its rules apply to the use of such.

The large or small-scale manufacture or production for sale purposes is strictly prohibited. Only research material that is no longer needed for research at KI or that has been rendered unusable may be considered for sale.³

Particular care shall be taken to observe the rules governing conflict of interest when the employee has an interest in a company purchasing disposed material.

6.2 Research data

Research data (raw data and documentation) generated by or included in a research project and regardless of the source of funding, is not the private property of the individual researcher or group, but remains the property of KI both during and after the project. The principle of public access also applies provided that the data is not protected by confidentiality.

7. Archiving

Research data shall be made accessible through registration and archiving (Karolinska Institutet's document management plan). KI's researchers are not entitled to decide for themselves what research data may be destroyed.

8. Support functions

KI employees who have produced IP and who intend to commercialise it may notify KI's innovation office for support.

In collaborations with American federal granting bodies as e.g. NIH, new discoveries must be reported in accordance with the specific demands of the body in question. KI's Grants Office may be contacted if necessary.

Grants Office may also be contacted for support with corporate collaborations.

³ Transfer of State Movable Assets Ordinance (1996:1191).