

PLEASE NOTE: This is a translation of the Swedish version. In the event of any discrepancy between the versions, the Swedish version is the official decision and the Swedish wording will prevail.

AGREEMENT

The following agreement on the training of medical doctors, clinical training¹ of certain other health professionals, clinical research and healthcare development has been entered into by Stockholm County Council (SLL) and Karolinska Institutet (KI), herein below jointly referred to as the parties. The partnership between SLL and KI as regulated in this collaborative agreement is based on the national ALF agreement (LS 1408-0934, KI 2-3594/2015).

Background

In September 2014, the Swedish government and concerned county councils entered into an agreement for the training of doctors, clinical research and healthcare development, herein below referred to as the national ALF agreement. The national ALF agreement became effective on 1 January 2015 and is supplemented by regional agreements between county councils and universities. The agreement covers both an expanded and deepened collaboration between the parties and a more detailed regulation of the management of ALF funds. The agreement derives from the county councils' responsibility for healthcare and the universities' responsibility for research and education, and thus the universities' need for collaboration with the healthcare sector to fulfil their obligations. The agreement is also intended to take advantage of the universities' ability to contribute to healthcare development at large.

In January 2001, the Swedish government and the former Federation of Swedish County Councils signed an in-principle agreement with the government assuming responsibility for the county councils' university-level healthcare training as of 1 January 2002, herein below referred to as the in-principal agreement. This agreement also describes the county councils' commitment to provide student training places, the remuneration to be paid by the government to the county councils for their participation, and the collaboration between the parties for the development of clinical practice. This agreement is supplemented by regional agreements between concerned county councils and higher education institutions.

This regional ALF agreement replaces the 2015 time-limited regional ALF agreement between SLL and KI based on the national ALF agreement, and the 2008 agreement between SLL and KI regarding collaboration for clinical training in certain educational programmes based on the in-principal agreement. It also replaces the agreement between SLL and KI regarding clinical training within the psychology programme.

¹ In this document, *clinical training* refers to the practical education of university students that takes place in a healthcare setting. In Swedish it is known as *verksamhetsförlagd utbildning (VFU)*.

Healthcare development in the Stockholm region

The Stockholm region is undergoing considerable change, which presents both opportunities and challenges. The population has increased substantially and is continuing to do so, with a demography characterised by an increasingly elderly and diverse population. These changes put pressure on the region's healthcare providers as regards both the volume and scope of their services. In addition to the public healthcare principal (SLL), there are a large number of private providers offering publically funded healthcare.

Patients are more knowledgeable and well-informed now than ever before. An increasing number of individuals are able to take greater responsibility for their own health, which creates ample opportunities for exploiting the potential of online healthcare initiatives by means of advanced medical informatics.

SLL invests heavily in the development of healthcare through not only the building and conversion of its physical infrastructure but also in information technology (IT) and other support functions as well as the restructuring of its organisation and management. The transformation of healthcare introduces new conditions for clinical research and education with an increasingly important role for primary and specialist care provided outside the emergency hospitals.

Access to patients and patient data is essential for education as well as for translational and clinical research. Access to ever larger patient groups with specific and precise diagnoses is needed in order to better understand pathogenic mechanisms and develop new therapies through large-scale analysis. Opportunities must therefore be in place for all patients in the Stockholm region to be invited to participate in, or contribute to, research projects and clinical trials. This requires, amongst other things, a cohesive and well-integrated information system.

SLL and KI collaborate closely on large infrastructural investments for research, education and development at the region's hospitals, primarily Karolinska University Hospital in Huddinge and Solna, with the aim to create internationally top-class conditions for healthcare, research and education. The parties' investments are expected to make a substantial contribution to the development of other life science activities in the Stockholm region.

The life science sector is a vital part of the region's commercial sector and is critically dependent on effective collaboration between the region's healthcare services and universities for its operation and growth.

Collaboration between the Stockholm County Council and Karolinska Institutet

§ 1 Declaration of intent

As a basis for this agreement, SLL and KI express a common intention to develop their existing partnership in order to jointly and decisively improve human health.

In entering this agreement, the parties agree to jointly promote the development of healthcare by deepening and expanding their collaboration in the fields of translational and clinical research, education, development and innovation. A common, long-term strategy will be developed for collaboration in academic healthcare in the Stockholm region.

Healthcare services shall create optimal conditions for translational and clinical research. The continuous establishment of internationally competitive clinical researchers and access to research time for clinically active research personnel shall be ensured.

SLL and KI shall together develop the field of informatics in order to effectively meet the needs for patient data from medical records, quality registries and biobanks, as well as other information required for healthcare and research.

Research results shall benefit patients through a well-developed organisation and process designed for knowledge application and dissemination within the healthcare sector, and through an effective innovation process. Collaboration with the business sector shall be developed in order to further advance these intentions.

Collaboration in the field of education shall cover all healthcare-related courses and programmes at KI. Teaching in the clinical environment shall include elements of inter-professional training in order to fulfil degree requirements and prepare students for careers in complex professional situations that require cooperation and collaboration with colleagues possessing a wide range of competencies.

The parties shall take into account within their own activities the agreements that have been reached and the shared objectives that have been set up within the framework of the collaborative organisation described in this agreement. Decisions regarding respective parties' resources are taken by SLL and KI, respectively, in accordance with each party's decision-making praxis; each party will maintain control over its own resources.

Further, the parties shall use their own decision-making and planning processes to support expanded and deeper collaboration. In order to facilitate access to each other's decision-making processes and the implementation of joint decisions, each party is to have representation with the right of opinion on the other party's relevant decision-making entities at different levels within the respective organisations.

Against this background, the parties agree on the following as a supplement to the national ALF agreement:

§ 2 Academic healthcare

Academic healthcare is regulated by the national ALF agreement and shall:

- continuously conduct research of a high national and international standard;
- conduct high-quality education;
- follow international developments in medical research, education and healthcare;
- contribute to evidence-based healthcare by translating research results generated both internally and externally into practical care, and to continuously evaluate established and new methods;
- disseminate results of their own activities to other parts of the healthcare services; and
- collaborate with the business sector and patient organisations.

The goal for SLL and KI is for all academic healthcare activities to attain a high level of quality and to contribute to healthcare development. This shall be achieved through the following means:

- creating conditions for research that contribute to scientific breakthroughs resulting in discoveries that change the knowledge of life processes and create opportunities to achieve good health and alleviate or cure disease;
- creating conditions for leading clinical training that meets high quality standards and the health services' need for well-trained medical staff;
- ensuring high-quality inter-professional education;
- ensuring that all doctoral education is of high quality;
- ensuring that all research is of high quality;
- developing cohesive healthcare processes in which new knowledge is translated into individually adapted prevention, early diagnosis and treatment; and
- creating opportunities for research results to be put to practical clinical use through an advanced innovation process in close collaboration with the business sector.

§ 3 Academic healthcare units

Academic healthcare is conducted within the healthcare system at academic healthcare units (AHUs). Within each AHU, research, education and healthcare development shall be considered to be core activities on par with healthcare services. This shall be reflected in the control and follow-up of AHU activities.

AHUs shall meet the requirements for academic infrastructure, competence and quality prescribed by the national ALF agreement, and shall be adaptable to the criteria set by the national ALF steering committee.

§ 4 The university hospital and other healthcare institutions involved in academic healthcare

Karolinska University Hospital shall play a central role in the clinical research and education conducted within academic healthcare. All university hospital units shall meet the demands placed on academic healthcare. Responsibility for ensuring that the hospital meets these needs and satisfies the necessary requirements for high-quality clinical research, education and development thus falls under the hospital management.

Further, SLL and KI agree that Danderyd and Stockholm South General hospitals, St. Erik Eye Hospital, as well as all academic healthcare clinics and all other authorised units within the Stockholm Health Care Services (SLSO) shall initially constitute AHUs.

Once this agreement has been entered into, criteria for the more detailed description of academic healthcare and its evaluation must be produced. Subsequently, academic healthcare shall be evaluated on the basis of the established criteria; based on the results, future AHUs will be defined. Regular evaluations should then be conducted at intervals agreed upon by the parties and with due consideration paid to any instructions issued by the national ALF steering committee.

All healthcare providers that are financed by the county council should be eligible to apply for AHU status.

Hospitals other than the university hospital with one or more AHUs are to be referred to as teaching hospitals offering academic healthcare.

§ 5 Academic healthcare in Stockholm's academic healthcare system

All county-council financed healthcare shall be able to contribute to the development of academic healthcare, for example by:

- supplying patient data from biobanks, quality registries and medical records,
- participating in research projects, clinical trials and other activities requiring direct patient contact or access to patient material,
- participating in clinical training, and
- participating in the application of knowledge.

Stockholm's academic healthcare system is the organisational term in this document for the interaction between all parts of the healthcare system and KI.

§ 6 The collaborative organisation

SLL and KI are jointly responsible for the governance of academic healthcare. This takes place within the collaborative organisation regulated under §§ 7-11.

In accordance with the national ALF agreement, collaboration in the Stockholm region is organised at the following three levels: (i) the senior management level, (ii) the hospital/equivalent level, and (iii) the operational level.

At the highest level (i.e. the senior management) SLL is represented by its executive leadership. KI is represented by the university management.

At the second level (hospital/equivalent), SLL is represented by the clinical line managers (hospital managers and divisional/theme managers or the equivalent) or by other employees. KI is represented by members of its management organisation and by its line managers (heads of department or the equivalent) or by other employees.

At the third level (operational) SLL is represented by clinical (or the equivalent) managers and its line managers or by other employees, and KI is represented by the departmental section/division/unit managers or by other employees.

Within the collaborative organisation, KI also has a representative in the university hospital management and in the management of teaching hospitals providing academic healthcare/the equivalent, and SLL has a corresponding representative in KI's management organisation. There shall be similar reciprocal representation in the following cases:

At the university hospital

- theme/function management, and management of corresponding clinical department at KI, and
- patient area/clinic management or the equivalent, and management of section/division/unit within the corresponding clinical department at KI.

At teaching hospitals providing academic healthcare/equivalent

- clinic management or the equivalent, and management of section/division/unit in the corresponding clinical department at KI.

Mandates and other conditions that result from the reciprocal representation shall be defined and established by the KI-SLL Management Group (§ 7).

§ 7 Senior management level

The KI-SLL Management Group, which comprises management representatives from KI and the county council, is the collaborative body at the managerial level. The Management Group shall comprise of up to 12 members, made up of an equal number of representatives from SLL and KI, appointed by the respective organisations. The group is chaired alternately by the SLL's chief executive and KI's president.

The Management Group has overarching responsibility for how the collaboration between SLL and KI is to be organised and conducted.

The Management Group also has responsibility, within the framework of the partnership regulated in this agreement, for strategic considerations and decisions necessary for the establishment and development of academic healthcare. It also decides which units shall be AHUs and how the different components of the Stockholm academic healthcare system are to interact.

The Management Group decides on the evaluation and follow-up of academic healthcare activities; on where clinical training is to be conducted; on long-term infrastructure investments; on the general ALF budget and the RD&E funds that SLL allocates to the partnership. It also decides on the calculation principles for costs; on the grounds of prioritisation; on the allocation and reporting of the funds covered by this agreement; and on reports, follow-ups and evaluations (see also §§ 12-14). The decisions of the Management Group may need to be prepared or approved by the decision-making entities of each party.

Two committees shall be assembled to support SLL's and KI's joint strategic work within the Management Group – one with responsibility for collaboration on matters of research and development (the Research Advisory Committee) and one with responsibility for collaboration on educational matters (the Education Advisory Committee). The committees shall also have responsibility for collaboration on matters of infrastructure and innovation related to research/development and education, respectively.

Each committee is to comprise an equal number of representatives from SLL and KI with a combined total of up to ten members at the start of the agreement period. This number may be changed if the parties so agree. Each committee shall also include a student representative appointed by the Medical Students' Union, and a medical resident representative appointed by SLL. Each committee is chaired alternately by SLL and KI appointees. The committees report to the Management Group.

To manage issues concerning clinical training that require coordination with other higher education institutions in Stockholm County, SLL and KI may invite these institutions to meet with the Education Advisory Committee. The KI-SLL Management Group decides the issues to be coordinated in this way. SLL also collaborates with other higher education institutions on matters relating to clinical training.

The Management Group may decide on other collaboration bodies.

§ 8 The duties of the committees

The Research Advisory Committee shall assess the need and initiate measures for the development of translational and clinical research, and of healthcare in general. The Research Advisory Committee shall also prepare calls for application for funds for translational and clinical research and take decisions on applications as directed by the KI-SLL Management Group.

The Research Advisory Committee shall also coordinate initiatives in areas such as the development of clinical and translational research environments, comparative medicine, biobanks, informatics and other costly research infrastructure.

When so tasked by the KI-SLL Management Group, the Research Advisory Committee shall draft proposals in consultation with the Education Advisory Committee for evaluation criteria and processes regarding existing and

prospective AHUs, monitor the development of AHUs over time, and initiate their evaluation following decisions by the KI-SLL Management Group.

The Education Advisory Committee shall assess the need and initiate measures for the development of KI's clinical training. The Education Advisory Committee shall plan and propose which healthcare units will conduct clinical training. Any change in direction or other action taken by each party that affects planning and scope shall first be put forward to the Education Advisory Committee for consultation.

The Education Advisory Committee shall also have responsibility for the development of learning environments that improve the integration of education, research and care. Furthermore, the committee shall work to facilitate the transition from studies to professional life through collaboration, taking into account SLL's future competence needs and the conditions required by its operations, as well as KI's requirements for high quality university education.

When tasked by the KI-SLL Management Group, the Education Advisory Committee shall also submit proposals for how the financial resources allocated to clinical training are to be utilised. The Education Advisory Committee shall also prepare calls for funding applications for pedagogical development and research and take decisions on applications as directed by the KI-SLL Management Group.

§ 9 Hospital level/equivalent

The hospital level refers to the university hospital and teaching hospitals offering academic healthcare/the equivalent. For each such unit, KI appoints a representative to the hospital/equivalent unit's management group following consultation with the hospital. Similarly, the university hospital appoints, after consultation with KI, a representative to the KI management group.

The university hospital's leadership (or its management at a theme or function level) appoints, following consultation with KI, representatives to the management groups of KI's clinical departments operating within the university hospital. Similarly, KI appoints, after consultation with the university hospital management (or its management at a theme or function level), representatives to the management groups at theme/function level.

The management of the teaching hospitals offering academic healthcare/the equivalent appoints, after consultation with KI, a representative to the management group of KI's clinical department within or closely associated to the hospital/equivalent.

For each hospital/equivalent concerned there shall be a RD&E Committee at the hospital level made up of an equal number of representatives from SLL and KI.

Each committee is chaired alternately by an SLL and KI appointee. The hospital director/equivalent and the president of KI appoint representatives for

their respective organisations in the RD&E Committee following an internal nomination process.

A hospital's RD&E Committee decides on the strategic utilisation of allocated resources and the distribution of resources to the operational level (clinic/equivalent), and carries out other tasks the KI-SLL Management Group so decides.

§ 10 Operational level

The operational level refers to patient area/clinic or other equivalent organisational unit contained within or constituting an academic healthcare unit (AHU). The organisational unit is hereafter referred to as an operational unit.

For each operational unit, KI (the head of the corresponding KI department) appoints, after consultation with the hospital director/equivalent or management at a theme/function level (of the university hospital), a representative to the management at the operational unit level.

The management of a clinic or other equivalent organisational unit appoints, after consultation with KI (the head of the corresponding KI department), representatives to the management of the section/division/unit or equivalent in the clinical KI department concerned.

Each operational unit shall have an RD&E Group made up of an equal number of representatives from SLL and KI where the unit management is included. Each group is chaired alternately by an SLL and KI appointee.

The hospital director/equivalent and the relevant heads of department at KI appoint representatives for each party in the RD&E Group following an internal nomination process.

The RD&E Group at each clinic/equivalent decides on the utilisation of allocated resources and carries out the tasks that the hospital's/equivalent's RD&E Committee so decides.

§ 11 Joint secretariat

The collaborative bodies receive administrative support from a joint secretariat for which both parties are responsible and which will be organised in a manner suitable to each party. The secretariat is staffed by people from administrative units within each party and perform their tasks within the scope and from the perspective of the collaborative body.

There shall be an RD&E Office at the university hospital to support the entire collaboration organisation by providing the processes and decision-making documentation required. The head of the RD&E Office is appointed by the director of the university hospital after consultation with KI's president. The position shall be held by an individual holding a combined employment.

§ 12 Financial resources

For the SLL-KI partnership, the government provides, through KI, ALF funding for clinical research and the training of medical doctors in addition to the remuneration paid by KI to SLL for certain courses in accordance with § 16.

Similarly, SLL allocates for its partnership with KI RD&E funding for the financing of clinical research and its clinical education commitments. The funds intended for education, research and development in academic healthcare (both government-supplied ALF funding and the regional RD&E funding supplied by SLL) shall be controlled through shared and agreed priorities and shall be clearly identifiable.

The KI-SLL Management Group annually establishes the level of resources to be available for joint prioritisation as per above. Additionally, the Management Group shall be able to gain an overview of the combined resources for clinical research and clinical education in the Stockholm region through reports submitted by the parties on the resources each one provides for additional activities that are not included in this collaborative agreement.

§ 13 Principal targets for resource allocation

The KI-SLL Management Group allocates resources for the following purposes:

- Infrastructure for clinical research and clinical education
- Competitive funding for clinical research and clinical education
- Activity-based funding for clinical research
- Funds for clinical education
- Special initiatives
- Healthcare development

Clinical research refers to such research that requires the organisation and resources of the healthcare services and that is designed to solve a problem of ill-health or identify factors that lead to greater ill-health. This includes research aimed at disease prevention.

§ 14 Basis for resource prioritisation

The KI-SLL Management Group shall:

- based on a long-term strategic perspective, establish a framework budget for shared infrastructure specifying financial sources and any user fees;
- set aside resources for the financing of the joint control, management, administration and communication of research and education activities, and for the costs of management and administration facilities for the clinical departments, and establish principles dictating how ALF/RD&E funds are to cover the clinical departments' costs;
- establish the purposes for which groups may apply for funding and the grounds for its distribution, and which collaboration body/ies shall prepare and decide on the allocation of resources to applicants; and
- establish an allocation model for clinical research funds distributed at the operational level by activity with particular focus on rewarding quality.

§ 15 Externally financed research

The principle of full cost coverage shall apply to all externally financed research conducted within the healthcare service. The KI-SLL Management Group decides on the regulations required for the application of this principle. Agreements entered into between KI and an external (third) party allowing this external party access to the healthcare services are to be preceded by consultations with SLL in accordance with procedures established by the KI-SLL Management Group. If SLL enters such agreements in areas in which KI conducts activities in the healthcare services, KI shall likewise be consulted in ways decided upon by the KI-SLL Management Group.

§ 16 Remuneration paid by KI to SLL for its educational commitments

KI remunerates SLL for its clinical training commitments within KI's occupational therapy, audiology, midwifery, biomedical laboratory science, physiotherapy, psychology, psychotherapy, radiography, nursing, specialist nursing and dental hygiene study programmes at a rate of SEK 1,510 per student and week of training (amount quoted at the 2015 price level).

This sum shall, in the same manner as the appropriations to universities and university colleges, be converted to current price levels taking account savings or cuts in expenditure that the Swedish parliament decides for these appropriations.

The Education Advisory Committee calculates annually the scope of clinical training as per above, expressed in number of training weeks, and based on the number of days students undergo training. Remuneration is paid in accordance with this figure.

The KI-SLL Management Group decides on more detailed regulations for clinical training remuneration.

Remuneration to SLL for the clinical components of the speech and language pathology study programme is taken from the ALF funds for the training of medical doctors.

§ 17 Disbursement of remuneration to SLL

ALF remuneration and the remuneration described in § 16 shall be paid by KI to SLL on a monthly basis on the day that KI receives government funding.

§ 18 Financial and operational reports of ALF remuneration and other jointly prioritised resources

The County Council is required by § 14 of the national ALF agreement to compile a financial and operational report on the utilisation of ALF remuneration broken down into research and education.

This report shall clarify how the ALF remuneration has been utilised for premises, salaries and other costs. The report shall be submitted to the university in time for it to be included in the university's own annual report.

In conjunction with the annual reporting described above, the parties agree to evaluate how the implementation of this agreement has helped to strengthen research, education and collaboration. The results of this evaluation are to be included in an operational report to be submitted to each party.

§ 19 Management of disputes

If a dispute arises that cannot be resolved, it shall be referred to the next highest level in the collaboration organisation. Any remaining disputes are resolved by SLL's chief executive and KI's president in a separate negotiation.

§ 20 Termination of agreement

This agreement ceases to be valid at midnight on 31 December of the year that falls two years after the agreement has been terminated.

§ 21 Period of validity

This agreement shall remain in effect as of 1 January 2016 and is effective on the condition that it has been approved by the SLL county council assembly and the KI University Board.

§ 22 Transitional provisions

Authorised units shall initially constitute AHUs until such time as an assessment has been conducted. This shall be done by 31 December 2018 at the latest. The parties acknowledge that it will take time to implement the new collaboration organisation, and it will not be fully operational when this agreement takes effect (1 January 2016).

Stockholm 27 November 2015

On behalf of Stockholm County Council On behalf of Karolinska Institutet

Toivo Heinsoo
Chief Executive

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