

Statement regarding confidentiality under the Public Access to Information and Secrecy Act in relation to authorities

In anticipation of performing future clinical trials, LIF member companies send study protocols to hospitals run by *inter alia* county councils for evaluation. According to standard procedure applied by most member companies, recipients must sign a confidentiality agreement prior to accepting the study protocol, which slows down the process with the review of the protocol. LIF has therefore investigated if study protocols may be protected by rules of confidentiality under law.

Documents which are submitted to a Swedish authority, in this case a county council, are public under Swedish law, with which follows a right of access to the documents. The Public Access to Information and Secrecy Act (2009: 400) (Sw. *Offentlighets- och sekretesslagen*) ("**OSL**"), however, contains provisions on confidentiality within the public sector and prohibits, under certain circumstances, the disclosure of public documents.

According to OSL Chapter 31 § 12, confidentiality applies, *inter alia*, to details relating to a scientific investigation or other such assignment which the authority shall provide for a particular person or legal entity, if it can be assumed that the assignment was submitted to the authority under the assumption that the details are not revealed. A study protocol, which is submitted in order for the authority to evaluate a potential collaboration, can therefore be subject to the rules of confidentiality under the applicable rule in OSL.

The provisions on confidentiality apply to authorities as well as to institutions which are comparable to authorities under OSL. A limited liability company, partnership, economic association or a foundation where municipalities or county councils exercise control is compared to an authority under OSL.

At present (31 May 2015), the following hospitals, institutions and entities active within health care, are operated in the form of a limited liability company, partnership, economic association or a foundation, and are controlled by a county council:

- Ambulanssjukvården i Stockholm AB
- Clintrials Skåne AB (during the year 2015, Teknopol AB, Innovator Skåne AB and Clintrials Skåne AB (all owned by the municipality of Skåne) will merge to form the company Innovation Skåne AB)
- Danderyds Sjukhus AB
- Folktandvården Gävleborg AB
- Folktandvården Skåne AB

- Folktandvården i Stockholms Län AB
- Folktandvården Sörmland AB
- Folktandvården Västmanland AB
- Sahlgrenska International Care AB
- Skåne Care AB
- S:t Eriks Ögonsjukhus AB
- Stockholm Care AB
- Stockholms läns sjukvårdsområde, SLSO
- Södersjukhuset AB
- Södertälje Sjukhus AB
- TioHundra AB

Study protocols submitted to the above mentioned entities will be subject to confidentiality under OSL Chapter 31 § 12, as will study protocols submitted to hospitals which are run by county councils or , in the exceptional case, a municipality. As the protocols are subject to an obligation of confidentiality under law, it will not be necessary to enter into a separate confidentiality agreement, although LIF member companies are strongly recommended to request in writing that confidentiality shall apply to the study protocol and that the recipient is reminded of his/her duty of confidentiality which follows from OSL Chapter 31 § 12. Please see Appendix 1 for an example of how the confidentiality request may be worded.

Privately owned hospitals however, such as Capiro St. Görans sjukhus, Capiro Närsjukvård, Capiro Specialist, Praktikertjänst AB and Sophiahemmet, where neither municipalities nor county councils exercise control over the companies, will not be subject to the rules on confidentiality under OSL. In order to ensure confidentiality in relation to these entities, LIF members companies should instead enter into a confidentiality agreement or have the institution sign a confidentiality undertaking, as is standard procedure today.

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Appendix 1

[◆] requests that the information contained in the annexed study protocol is handled confidentially in accordance with the provisions of Chapter 31 § 12 of the Public Access to Information and Secrecy Act (Sw. Offentlighets- och sekretesslagen).

The recipient is hereby reminded of his/her duty of confidentiality under Chapter 2 § 1 of the Public Access to Information and Secrecy Act (Sw. Offentlighets- och sekretesslagen) and that the right to communicate and publish information in accordance with Chapter 1 § 1 of the Freedom of the Press Act (Sw. Tryckfrihetsförordningen), the so-called freedom of information (Sw. meddelarfrihet), is restricted with respect to the information.