

Rules on Intellectual Property and Publications of Core Facilities (CFs) in Chemistry I Division of MBB

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**Karolinska
Institutet**



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Introduction

Core facilities have the purpose to support research with expertise and techniques in advance infrastructure. A clear policy handling research data, intellectual properties and scientific collaborations is readily required.

The present policy is based on the following main regulatory documents:

1. *“Guidelines on intellectual property and corporate collaborations”*, Ref. 1–610/2017, effective as of 1 January 2018, replacing the document 3195/03–600, and valid until further notice.
2. *“Professor’s privilege”*; cf. the Act on the Right to Inventions by Employees (SFS 1949:345) and the customary practice at Swedish universities.
3. *Swedish Act on Copyright in Literary and Artistic works* (SFS 1960:729)
4. *Swedish Patents Act* (SFS 1967:837).
5. Wikipedia (www.wikipedia.org)
6. *CODEX – Rules and Guidance for Research (VR)*, www.codex.vr.se/en/etik2.shtml
7. *Public Access to Information and Secrecy Act* (Swedish Code of Statutes – SFS 2009:400).

Purpose

A policy to outline the operations at the Proteomics Biomedicum Core Facility is aimed to provide information **to facility users** about handling research data, intellectual properties and scientific collaborations.

I. Definitions

I.1. Intellectual property (IP) – whatever constitutes the product of intellectual work, such as inventions, knowledge, methods, protocols, texts, compilations, information, calculations, computations and drawings. IP may have legal protection (e.g., patent, copyright, trademark and design protection), but not necessarily [1, 4.1].

I.2. Research data – raw data and documentation describing how they were obtained, generated by or included in a research project. Research data are unchangeable; they cannot be corrected or improved at will. They are not IP. They belong to KI, which is a public institution. According to the Swedish *Public Access to Information and Secrecy Act*, non-secrete data belonging to a public institution must be archived, with archives being non-confidential and publicly available [1, 6.2; 7].

I.3. Researcher – every KI (and other university) employee or associated person performing scientific work (as opposed to technical, administrative, etc.) regularly (or irregularly but frequently). Ref. 1–610/2017 makes no distinction between CF staff and other KI personnel in calling them researchers [1]. Teachers are also considered researchers in some context (e.g., in “professor’s privilege” [2]), but some other texts speak of “researchers and teachers” (e.g., [1]).

I.4. Creator – a person who has created a literary or artistic work [3], or came up with an idea [3] or an invention [4], or has created IP by e.g. extracted information from Research data, drew a scientifically sound conclusion from Research data, or has generated a scientifically plausible hypothesis [5, “creator”].

I.5. Ownership – having absolute rights and legitimate claim to an object or IP, with or without physical possession of this object or IP documentation [5, “ownership”].

I.6. Information – new facts partially or totally resolving the existing uncertainty; alternatively, data on an unexpected discovery or event that may increase the uncertainty. The less expected the facts are, and the more uncertainty they change, the more information they contain [5, “Information”]. According to I.1, information is IP. Information always has a creator, who according to I.4 is the owner of the generated IP.

I.7. Data analysis is a process of inspecting, cleansing, transforming and modelling Research data with the goal of discovering useful information, forming conclusions and supporting decision-making [5, “Data analysis”]. Any treatment of Research data that can be done in multiple ways is Data analysis. Choosing only one out of the multiple possible ways of Data analysis reduces the uncertainty, and thus is information. Thus, Data analysis always produces new information, and thus it generates IP.

I.8. User fee – the payment of the Customers to CF for producing Research data from their samples.

I.9. Rare or Unique method – an analytical method that has been used in few (e.g., <10) research articles explicitly, and/or by few (e.g., ≤3) research groups. This is in contrast to a Conventional method, that has been explicitly used in many (e.g. ≥10) research articles explicitly, and/or by many (e.g., >3) research groups. Rare or Unique method can be in sample preparation, experimental design or workflow, or data analysis.

I.10. Research – an occupation always associated with producing new information, and thus generating new IP. The use of a Rare or Unique analytical method is always considered to be Research.

I.11. (Scientific) Service – an occupation associated with producing Research data from a third-party (Customer, User) samples. Service is performed using Conventional analytical methods and generates no IP.

II. Basic principles

II.1. Researchers, teachers and students, including undergraduate students, that created IP, have ownership of it regardless of the funding source for the research that led to IP generation [1, 4.6]. All IP creators are recognized by Ref. 1 as having “professor’s privilege” defined in Ref. 2.

II.2. KI has the right of use to IP created by KI researchers, teachers and registered PhD students for the purposes of research and teaching activities. Undergraduate students are not considered KI employees, and this rule doesn’t apply to them [1].

II.3. The researchers own the IP they created fully and as individuals [2], regardless of the position they occupy, whether it is in a CF or a research group, whether they are employed 100% or less, or get no salary from KI at all. Ownership of IP means that the researchers can transfer it for compensation (sell) to other individuals, companies, government agencies, etc., or give it away, e.g., by transferring to public domain. KI, its departments, researcher groups, and individual researchers at KI who are not the IP creators have no material influence on these decisions and cannot order a KI researcher to dispose the IP they own in a specific way, unless this is explicitly written in their employment contracts.

II.4. Anyone who gave no intellectual input in producing IP is not considered creator of that IP. This is regardless of whether this person is a KI researcher or not, and whether or not this person provided technical and/or administrative help, and/or material of non-unique nature that were involved in IP creation [3-4]. The author of a Rare or Unique method materially used in the study is always considered to contributing an intellectual input into the study.

II.5. With rights comes responsibility. The IP creator is responsible for the veracity of the underlying information, and can be made responsible to prove it in case this IP is disseminated, such as in publications, patents, presentations, etc. This is so even if the creator has transferred the IP ownership to a third party.

II.6. Regarding the authorship principles, they are still discussed by the global scientific community. A special group of the *Council of Science Editors* (CSE's Authorship Task Force) has been created to debate the issues and prepare guidelines. However, there has been a consensus view saying that the authors *should be able to explain why and how the observations were made, and how the conclusions follow from the data* [6]. Therefore, the creators of information used in the paper should as a rule be co-authors.

III. Specific IP rules for CFs

III.1. CFs can conduct *Own research*, *Contract analysis*, *Collaborative analysis and Collaborative research*. The Customers must choose before the sample submission whether they want to perform Contract analysis or Collaborative research.

III.2. Own research at CFs can concern only Method development for their research area; all other research purposes are pursued by other research groups. Own research of CF is funded by the competitive grants obtained from KI, SciLifeLab, VR or other agencies. All IP produced in Own research belongs to CF Researchers.

III.3.1 In **Contract analysis**, also known as *Service job*, the Customer provides samples with a certain scientific question in mind and formulates an analytical task for CF addressing the scientific question, while CF chooses a Conventional analytical method, prepares samples, performs a standard analytical experiment and delivers to the Customer *Research data*, without Data analysis. No new IP is generated in this process [1.2].

III.3.2. Contract analysis is funded by the User fees [1.8]. Note that the User fees do not cover *Data analysis* by CF.

III.3.3. Neither covers the User fee a *Method development*, should it be desired for performing Customer's analysis. Thus, if there is no Conventional analytical method addressing the posed analytical question, CF cannot perform Contract analysis. Instead, CF can either use Rare or Unique analytical method, or attempt to develop a new analytical method, both within Collaborative research (see III.4.1).

III.3.4. In Contract analysis, Customer retains whole ownership on the IP related to the provided samples and scientific question, but also bears full responsibility for the veracity of the interpretation of these data in relation to the scientific question posed (see IV.4.2).

III.3.5. The Swedish law [7] requires all Research data to be archived and made publicly available [1]. In Contract analysis, upon CF transferring Research data to Customer, it is Customer's obligation to follow these regulations and provide archiving and public access (usually after publication), as these functions are not covered by the User fee.

III.4.1. In **Collaborative analysis**, CF performs first Contract analysis generating Research data (without IP being produced), for which it collects a User fee from the Customer. Besides that, CF also performs Method development and/or Data analysis. The latter is not covered by the User fee, but is funded instead by the grants from KI, SciLifeLab or VR, other agencies that CF wins in competition with other CFs.

III.4.2. By asking CF to perform Method development or Data analysis, the Customer engages in Collaboration with CF, as defined by the Item 5 of 1–610/2017 “*Principles of collaborative and contract research*”.

III.4.3. The IP produced in Method development, such as protocols, workflows, specific use of instruments and chemicals, etc., belongs to CF researchers, unless the intellectual contribution of the Customer was material for the method development, in which case the generated IP is a joint property of CF and Customer. The IP produced by CF in Data analysis is always a joint property of CF and Customer.

III.4.4. The Research data produced by CF in **Collaborative analysis** will be archived and made publicly available by CF (usually after publication) according to the Swedish law [7].

III.5. The Customer may wish to acquire the IP created by CF researchers in performing Collaborative analysis on Customer’s samples. In such case the IP rights will be transferred from CF to Customer against a separate compensation. The rules for such transfer are based on the principle II.3 (IP is the property of creators as individuals and not as KI employees) as well as the KI Rule that external as well as internal funding obtained by KI, regardless its origin, cannot be used for e.g. patenting KI researchers inventions, as the latter benefit them as individuals and do not directly benefit KI as organization (source – MBB administration). Therefore, the conditions of the IP transfer by CF researchers to other IP owners is a subject of negotiations between the IP owners, unless there is a special condition explicitly written in CF researchers’ employment contracts.

III.6. In **Collaborative research**, CF is part of the grant application together with Collaborator(s), where CFs role is the development of a new analytical method and its application to Collaborator’s analytical problem. In

Collaborative research, CF has its own budget, and CF's work within the project is funded by this budget. All IP related to the new method itself is CF's property, unless the Collaborator's intellectual input into it is material, while the results of the analysis of Collaborator's samples are always a joint property of CF and Collaborator(s).

IV. Publication rules for CFs

IV.1. In Contract analysis, there is no requirement of the inclusion of CF researchers in the list of publication authors, as no IP is generated by CF in this type of work. However, the contribution of CF is encouraged to be mentioned in the *Acknowledgements* section.

IV.2. All Collaborative analysis and Collaborative research should eventually be published, according to the item 4.7 of Ref. 1 that stipulates: *"It is incumbent upon the researcher to ensure that his or her research is published or otherwise made available to the public"*. Also, item 5 states that *"The collaboration must allow KI researchers and students to publish their research findings."* Thus, CF researchers have the right to insist that the findings of their Collaborative research be published. As a rule of thumb, all Collaborative projects should be included in a publication in one form or another.

IV.3. Usually, it is the Customer that initiates writing the manuscript based on the Collaborative work. In exceptional cases, CF can take the initiative in writing the manuscript.

IV.4. The authorship rules are governed by the CSE consensus principle that the authors *should be able to explain why and how the observations were made, and how the conclusions follow from the data* [II.6].

IV.4.1. In Contract analysis, where CF produces Research data and generates no IP (III.3.1), the Customer must take all responsibility for the veracity of data interpretation (III.3.4), and for data archiving and providing public access (III.3.5). CF only guarantees that the Research data are produced from Customer's samples according to Conventional protocols and methods, using properly maintained and calibrated instruments.

IV.4.2. In a warning example, the Customer expects the molecular mass of the compound to be 531.237 Da, while the MS data produced by CF contain a number of ions, one of which has m/z of 531.238. The Customer reports in a manuscript (where CF researchers are not co-authors) that mass spectrometry confirmed the expected molecular mass. However, if an inquisitive Reviewer wants to inspect the raw data, the Customer must be able to provide this without the help from CF, who are not obliged to store such data. It may turn out that the ion in question was not M^+ , but $[M - NH_3 + H]^+$, or any other type of ion, and thus the Customer's conclusion was an error. CF would however bear no responsibility for this error, because it emerged from data analysis performed by the Customer and not the analytical experiment performed by CF.

IV.5. In Collaborative analysis and Collaborative research, the basic principle is that the CF researchers must always be included in the author list as the IP (co-)creators and (co-)owners.

IV.6. The same applies to patents and other legally protected IP. Violation may have legal consequences (e.g., the patent may be declared invalid if not all creators are declared as the inventors).

IV.7. As a rule, if the main message of the publication is the biological or medical question posed by the Customer/Collaborator, and the results of CF research are used as a supporting evidence, the CF researchers should become junior authors, and the Customers/Collaborators – senior (first) and corresponding authors.

IV.8. However, if the main message of the publication is the information provided by CF research, while Customers/Collaborators provided samples of non-unique origin (*i.e.*, they could be replaced by other samples available to CF), the CF researchers should become senior (first) and corresponding authors, and the Customers/Collaborators – junior and co-corresponding authors.

IV.9. If the values of the intellectual contribution of the Customer/Collaborator and CF researchers are approximately equivalent, both should be senior (first) and corresponding authors.

IV.10. In deciding which CF researchers should become authors of the manuscript resulting from Collaborative analysis or Collaborative research, the following results from the basic principle IV.1:

- The researcher(s) who developed the employed method of sample preparation, LC-MS/MS analysis or Data analysis, if it is unique or rare, must be included.
- The researcher(s) who participated in and contributed materially to experiment planning, Data analysis, quality control, verification, evaluation or interpretation of the data, must be included.

IV.11. All authors, junior as well as senior, must be able to get access to the manuscript draft and have enough time (reasonably limited) to read and contribute to it, as well as approve it, before the manuscript submission [6].

IV.12. Publication of the results of Own (non-collaborative) research is a right and responsibility of CF.

V. Implementation of the above Rules

V.1. These Rules apply to all work performed by CSs in Chemistry I Division of MBB. Responsible for their implementation and following are (in the order of authority):

- Division head;
- CF managers;
- CF researchers;
- Customers.

V.2. These Rules become valid from the Starting date, which is October 1, 2020, on which date they supersede all previously made agreements, unless specifically negotiated, but in any case, no later than one month past the Starting date.

V.3. These Rules must be sent for review to the Legal Department of KI no later than the Starting date, and in the absence of a banning order, they will

remain valid during the whole time of the review and eventual amendment period.

V.4. To ensure that the Customers are aware of these Rules when submitting the samples for analysis at CF, the following information should be made prominent on the submission form:

Choose and/or:

- **Contract (service) analysis** / Research data acquisition. No Data analysis or interpretation will be provided by CF; archiving and public access is Customer's responsibility; no IP will be retained by the Core Facility; no authorship demand by CF. User fee will be applied.
- **Collaborative analysis** / Besides Research data acquisition (for which the same User fee will be applied as in Contract (service) analysis), Data analysis and interpretation will be provided; archiving and public access will be provided; IP will be shared & authorship will be shared (see *Rules on Intellectual Property and Publications for details*).

The Customer must explicitly acknowledge that they have read and understood the Rules.

V.5. To secure Rules' implementation, all Collaborative analysis and Collaborative research projects must have Project descriptions written by CF managers together with Customers and approved by the Division head. To facilitate this process, CF managers will develop standard forms for new Project descriptions and examples of the correctly designed Project descriptions.