International Journal of Advanced Research in Biological Sciences
ISSN: 2348-8069
www.ijarbs.com
(A Peer Reviewed, Referred, Indexed and Open Access Journal)
DOI: 10.22192/ijarbs Coden: IJARQG (USA) Volume 9, Issue 8 -2022

Research Article

DOI: http://dx.doi.org/10.22192/ijarbs.2022.09.08.001

Necessity for changes under the Material Transfer Agreement

Christoph Gerst*, Paula Hasselmann, Raees Ahmed
Legal Department, Universitätsmedizin Göttingen, Germany
*Corresponding author: Christoph Gerst
E-mail: *christoph.gerst@med.uni-goettingen.de*

Abstract

In the present case, the problems and the resultant request of changes within the framework of negotiations on Material Transfer Agreement's by the staff unit of right of the Universitätsmedizin Göttingen have been examined for their frequency.
The trouble spot over the applicable law has become particularly clear, which is important for international contracts with contract partners of other jurisdictions. But also the points about confidentiality and anonymized data processing lead to requests for changes in the negotiations.
Nevertheless, the Material Transfer Agreement's have an important legal function for the exchange of informations and materials for scientific purposes. It is also important to be aware of points of conflict of this type of contract to prevent damages to the bond of trust of a contracting partner and eventually to the basis of the research relationship.

Keywords: MTA, Agreement, Negotiation, Confidentiality, Data processing, Germany

I. Introduction

The scientists often need to obtain materials (tissue samples, cell lines, plasmids, specially bred animals, algae, and so on) from other researchers or from relevant biobanks for their own research projects. A safe and proven method to obtain materials for research projects is to enter into a Material Transfer Agreement. In this contractual, synallagmatic exchange relationship, the Supplier agrees to provide the requested material, while the Recipient agrees to use it only for its specifically-designed research project.

The following elaboration uses an empirical study to deal with the common issues and related change requests on the part of the German Recipient/Supplier when entering into a written Material Transfer Agreement.

II. Amount of data collected

The data-in-use refer to the period from August 2018 to August 2020, during which various Material Transfer Agreements were concluded and/or negotiated in the legal department of the Universitätsmedizin Göttingen.

The Material Transfer Agreements focused on the distribution of plasmids from the Addgene repository (an international nonprofit plasmid and data resource) were not included in the assessment. Here, instead of separate material transfer agreements, a standard Addgene Material Transfer Agreement ("MTA") was pre-screened and negotiated. In particular cases, only the compliance of the draft with the template is checked. Besides, the Material Transfer Agreements that have been carried out as part of joint research projects or concluded with scientific consortiums are excluded from consideration. In this case, there is usually no separate Material Transfer Agreement. Instead of this, the transfer of relevant study materials is already regulated in the collaboration agreements or project descriptions declared as applicable to such studies. Finally, non-negotiated Material Transfer Agreements are also excluded from consideration. This applies to the case in which, after a Material Transfer Agreement has been negotiated, such an agreement is used again and again at any time thereafter on a consistent basis. Only the Material Transfer Agreement that was actually negotiated was included in the assessment.

A total of 34 Material Transfer Agreements were concluded during this period. In 47% of cases as shown in Fig. 1, the contractual partners predominantly included university partners, but research institutions and companies have also entered into contractual negotiations with the Universitätsmedizin Göttingen (UMG) as recipients or suppliers. The Universitätsmedizin Göttingen was the Recipient in 26 cases and the Supplier of materials in 8 cases; 23 cases are international in nature, i.e. materials are transferred abroad.

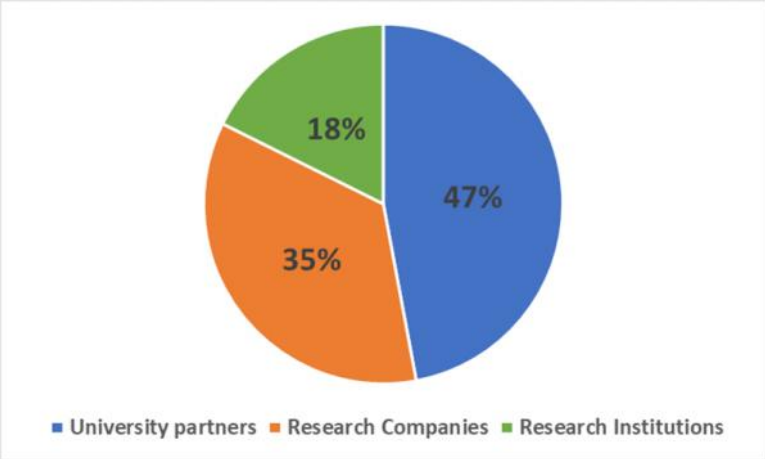

Fig. 1: Contractual Partner, analyses of 34 Material Transfer Agreements

III. Contractual provisions

The Material Transfer Agreement is a set of rules governing the transfer of research materials of data between institutions for research purposes (Kahl et al., 2018.) Although there is no bound form for the Material Transfer Agreement, and they all look very much alike due to the fact that the same exchange relationships are governed. A further similarity arises from the fact that the Material Transfer Agreement is a contractual agreement. Therefore, it should come as no surprise that the same types of articles appear again and again in different drafts of the Material Transfer Agreement.

However, the wording of individual paragraphs may be substantially different, although their content is the same. Reservation clauses may be formulated on a unilateral basis in favor of the Recipient of the materials or vice versa. However, the goal of treaty negotiation should always involve a fair balance between the interests of the Parties. Unilateral abuse of authorities puts

a strain on the trust-based relations between the Parties, and thus destroys the necessary basis for research relations. If this happens more often, it will only increase the cost for legal advice. Therefore, from our point of view, the reservation clauses formulated on a unilateral basis are counterproductive.

Nevertheless, negotiations are ongoing even with respect to consistent and fair reservation clauses, if only because different readers may construe the same reservation clauses differently. According to our sources, we were able to determine which parts of the Material Transfer Agreement required contractual negotiations and which compromises were reached. We combine this with the hope that future contractual negotiations will be more purposeful. In those instances where an objection is expected and then fallback wording is proposed anyway, that fallback wording may be added to the text of a treaty. This will at least save you a whole round of review on this item.

We have used the categories of reservation clauses available in the Material Transfer Agreements as a benchmark here as shown in table 1. They are practically the same everywhere and include: contractual partner, subject of an obligation, liabilities, property and ownership rights, confidentiality, fees, billing and others. By using these categories, we identified where the contracting Parties, who had received a draft of the Material Transfer Agreement for review, noted the change requests. The drafts of the Material Transfer Agreement are created and provided almost exclusively by the Suppliers of the materials, so that in most cases the Recipient carries out the first review. Furthermore, we noted where agreements had been reached, as well as which agreements had been reached on these points subject to further discussion.

Table 1: Necessary changes in the Material Transfer Agreements, analyses of 34 Material Transfer Agreements

	Revision accepted	Revision not accepted	Still pending	Total
Applicable law	9	4	2	15
Introductory clause/ Contact details	13	0	0	13
Confidentiality clause	5	0	1	6
Liability	3	1	1	5
Scope of services	3	1	1	5
Formal requirements	4	1	0	5
Ownership and possession rights	1	2	0	3
Publications and Changes	2	2	0	4
Termination	1	0	0	1
Remuneration	3	0	0	3

1) Applicable law

What stands out above all is the need to amend the clauses of the law applicable in the event of a conflict, which has been criticized very often, namely in 15 cases. Thus, in 23 cases of transboundary movement of materials, this clause was therefore negotiated by 65%. The lack of regulation and thus the preservation of silence, as well as four-time application of Belgian, Swiss or German law were accepted as a compromise. In another four cases, where the issue of applicable law was especially acute, such a compromise could not be reached. This applies, for example,

to the cases when the providing biobank was a state-owned institution, so that it could not have any other applicable law except for the national law. The remaining two cases have not been resolved at the time of publication. If a compromise cannot be reached, it will depend significantly on the relevant regulations in the respective research institution. The agreement governed by foreign law means that a complete risk assessment is no longer possible. Appropriate visual inspection may be performed in some legal circles, primarily because of the lower risk-weight density in the Material Transfer Agreements compared to the Clinical Trials in Human Beings. However, some legal systems are so far away from the German law (e.g. UK law or US law) that such a visual inspection involves too many risks.

Therefore, such remote rights can only be accepted after an appropriate internal risk assessment and after approval by the governing bodies. Here, in turn, everything will depend not only on the legal aspects, but also of each specific case, above all, how the importance of the research project will be considered, what kind of material will be transferred, how dangerous it is, whether it is in circulation, whether it is potentially suitable for patents and whether related patents can be expected to be granted.

2) Introductory clause/Contact details

Besides, the contact details of the Universitätsmedizin Göttingen were subject to changes – in 13 cases. The contractual partner often did not recognize that the Universitätsmedizin Göttingen was a state-owned institution, but not a company, and made a corresponding registration in the corresponding directory of the draft contract. Likewise, the contact details of the contractual partner – the Universitätsmedizin Göttingen – also had to be changed more frequently. However, this change request was always accepted without any problems. In practice, viewing the partner's imprint on its homepage proved to be useful during formation of a contract. If the responsible person named there was used in the Material Transfer Agreement, the need to make changes was eliminated.

3) Confidentiality clause

The confidentiality clause required revision in six cases. The desired processing of anonymized data instead of a complete lack of regulation or processing of pseudonymous data has been added in almost all cases. Optionally, a general Non-Disclosure clause has been added. Only in one case the acceptance of changes is still pending.

The Non-Disclosure clauses are of particular importance because of the connection between the transfer of material and a specific research project. Especially when it comes to the commercial suppliers or industrial suppliers of materials, the applicants (subsequent recipients of materials) usually must explain in detail why they need certain materials. In other respects, the provision of material will always be based on a specific research project. The researcher, in turn, is interested in taking charge of the communication upon its research project and, above all, in preventing early, unauthorized disclosure to the public in order to prevent any other inventions or publications.

4) Liability

At the same time, the issue of liability with five change requests often provoked disputes.

The appropriate indemnification clause or limitation of liability of the provider, which is generally unwilling to indemnify for damages caused by the use of the materials, and also does not guarantee the availability of certain research results through the material, makes no matter. Rather problematic were only those provisions in which the contractual partner offered a warranty liability. Within the limits of German legislation, this type of liability would also apply in addition to the contractual claims based on the fault. Thus, in the context of warranty liability, it no longer matters for the party bound with the obligations to such a clause whether it is liable for the damages. Instead of this, the party would be liable under the

warranty terms after the damage occurs, whether it is responsible for the damage or not. The Universitätsmedizin Göttingen does not accept such warranty terms because of the associated high risk of liability. Instead of this, a liability is sought that complies with the legal requirements of the German Civil Code, namely the need to be liable. When referring to the case of three Material Transfer Agreements, the latter was negotiated, while in one case, the insistence on the warranty liability, among other things, resulted in the loss a contract.

5) Scope of services

Another frequent change request from the Universitätsmedizin Göttingen was the insertion of the Subject of an obligation. The intention to exchange materials is quite often stated in the preamble, but then it has been "forgotten" to mention this exchange in the contract. Against this background, in five cases we tried to establish a clause obliging the supplier (not the Universitätsmedizin Göttingen) to deliver the materials when entering into the contract or to arrange for the delivery of the material without guilty hesitation. This clause was accepted in three cases out of five and was rejected by only one contractual partner.

6) Formal requirements

Besides, the formal requirements laid down in the contract had to be changed in five cases. However, these requirements have a specifically German background, because in accordance with 415f et seq. of the Code of Civil Procedure, the documentary evidence can be lodged with a court of law only as the original document (Siebert, in: Saenger–ZPO, 2019). However, original document can only be replaced by an electronic document, if it is given under a "qualified electronic signature" within the meaning of § 126a of the Civil Code in conjunction with the Fiduciary Services Act on the basis of the Regulation 910/2014. To date, neither DocuSign nor other scanned PDF signatures have the status of such a qualified electronic signature. In the contracts, the requirements for written form have been adjusted four times in five cases.

7) Ownership and possession rights

In addition, ownership and possession rights were problematic. In a Material Transfer Agreement, the contractual partner obtains the outright ownership of the research purposes, but ownership usually remains with the Supplier. However, the modifications, and therefore the research results are usually owned by the Recipient of the material. What is especially important here is the definition of what is meant by modification. In three cases this was not recorded in writing, in fact in one case, despite the corresponding need for changes, the modifications and related results were recognized as joint property. The proposed amendment was also not accepted during further contractual negotiations.

8) Publications and Changes

Finally, it also became necessary to negotiate a contract with regard to the rights of publication of the research results. Changes were agreed upon in only half of the four cases.

9) Termination

In almost all cases, the first draft contracts already contained relevant provisions on termination and Contract validity period. In particular, these provisions were elaborated by mutual agreement, and termination was possible only if there was a valid reason. The always desired clause on the ordinary Termination Exception was added to the contract in only one case.

10) Remuneration

The Subject of an obligation was basically problem-free clause and only once needed to be supplemented with the cost of material and the research project with the material. The fees and billing provisions were challenged only three times and, in accordance with the change request, were accepted without further problems.

IV. Conclusion

One final comment is that the law applicable in the event of a conflict most often causes the need for changes. A compromise proposal to remain silent seems to be the most preferable. However on other issues, such as confidentiality and processing of anonymized data, which is desirable here, there is a pronounced tendency towards the repeated change requests.

V. Acknowledgments

We would like to express our sincere gratitude to IJARBS Journal for publishing our article.

VI. Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

VII. Funding

The author received no financial support for the research, authorship, and/or publication of this manuscript.

VIII. References

Kahl, L., et al., *Opening options for material transfer*. Nat Biotechnol, 2018. **36**(10): p. 923-927.

Siebert, in: Saenger –ZPO, 8. Auflage 2019, § 418 Rn. 3.; BGH, Urt. v. 08.03.2006 - IV ZR 145/05 (22).

Access this Article in Online

Website: www.ijarbs.com

Subject: Legal Studies

Quick Response Code

DOI:10.22192/ijarbs.2022.09.08.001

How to cite this article:
Christoph Gerst, Paula Hasselmann, Raees Ahmed. (2022). Necessity for changes under the Material Transfer Agreement. Int. J. Adv. Res. Biol. Sci. 9(8): 1-6.
DOI: http://dx.doi.org/10.22192/ijarbs.2022.09.08.001