WWJMRD 2021; 7(10): 86-93
www.wwjmrd.com
International Journal
Peer Reviewed Journal
Refereed Journal
Indexed Journal
Impact Factor SJIF 2017: 5.182 2018: 5.51, (ISI) 2020-2021: 1.361
E-ISSN: 2454-6615
DOI: 10.17605/OSF.IO/6HQU8

Christoph Gerst PhD
Legal Department,
Universitätsmedizin Göttingen,
Germany.

Paula Racket
Legal Department,
Universitätsmedizin Göttingen,
Germany.

Raees Ahmed PhD
Legal Department,
Universitätsmedizin Göttingen,
Germany.

Correspondence:
Christoph Gerst PhD
Legal Department,
Universitätsmedizin Göttingen,
Germany.

Academic Research and Development Contracts at a University in Germany

Christoph Gerst PhD, **Paula Racket, Raees Ahmed** PhD

Abstract
The following article explains the different types of academic research collaboration form a legal point of view in Germany. The authors identify three main types of contracts: Grant/Funding agreements, contract research, and collaboration agreements. All three types have different legal consequences, which are important to know for any foreign entity who is thinking about collaborating with a German University in the field of academic and/or contractual research. It is important to notice, that the intention and expectations of the parties to the academic research collaboration define also the scope of the contractual clauses and thus are essential to the classification of the agreements. Sometimes those expectations become clear to the parties through the contract negotiations. The authors therefore underline the specific clauses who have to be kept in mind for this, which are in most cases clauses regarding (i) the results of the academic research collaboration and (ii) the IP-rights.

Keywords: Agreement, Clinical Trials, Academic Research and Development Contracts, Germany

Introduction

Clinical research and development play a central role in healthcare. It deals in particular with the experimental testing of new methods of treatment, new drugs, medical devices, or their further development, and the effectiveness and optimization of (new) therapeutic procedures. Clinical research includes all studies using human volunteers in order to obtain scientific knowledge.[1, 2] The main goal is to ensure better patient care.[3,4]

Clinical research is essentially carried out with the help of studies. In general, a distinction can be made between medicinal product and medical device clinical trials and other research projects, such as basic research, methodological research, laboratory research, or animal research. In principle, a medicinal product or medical device clinical trial exists if the subject of the study is the investigation, development or further development of a medicinal product or medical device.[5] The differentiation is extremely complex in individual cases and the wrong classification can lead to criminal violations. Therefore, separate departments are usually set up for this purpose, which deal exclusively with the classification of the study.

In the case of studies according to the Medicinal Products Act and the Medical Devices Act, it is a legal requirement that a so-called "sponsor" be named. A sponsor is a natural or legal person who is primarily responsible for the conduct of the study and who is also externally liable (so-called regulatory sponsor).[1,7-10] However, a person who is primarily responsible for the study and thus acts "like a sponsor" is also common in other research projects.[11,12] The decisive factor is who has control over the processes and who is or wants to be responsible for the overall process of the study, almost like a "General Contractor". This general contractor assumes liability.[13]

In practice, pharmaceutical companies or medical device manufacturers often commission medical facilities (for example, hospitals, doctors' offices) to recruit and treat patients involved in clinical research.[14,15] As a rule, in such cases, the companies act as regulatory sponsors and thus as the general contractors with overall responsibility. The regulatory classification of sponsorship is usually based on the actual responsibility and not on the designation of the sponsor. The person who is responsible for the entire process, the

entire study implementation, is to be regarded as the regulatory sponsor, in other words, the person who initiates and finances the study and significantly determines the manner of implementation.[16] The aim of carrying out the study is data collection for commercial use by the sponsor, for example, for the (market) approval of drugs[17] or as part of the conformity assessment of a medical device.[18] As a general contractor with overall responsibility, the liability of a company in individual cases in Germany can go so far that it is liable as a general contractor with overall responsibility under Section 13 of the German Minimum Wage Act (MiLoG) in conjunction with Section 14 of the German Posted Workers Act (AEntG), if its contractor does not pay his own employees the statutory minimum wage.[19]
In this situation, the medical facilities that recruit and treat the study participants and thus provide subsequent evaluation of the necessary data base are only service providers for the sponsor. The medical institutions thus conduct contract research and a study center contract is concluded as a type of service contract.[20]
A distinction must be made between configurations in which the medical institutions do not act as service providers for the company, but take on so many responsibilities in the study that they either become the sponsor or general contractor themselves, or at least take on an equal partnership role alongside the company. In the first case, an Investigator Initiated Studies (IIS) or an Investigator Initiated Trials (IIT) would take place, in which the entrepreneur (or a foundation, etc.) is the sponsor in material or financial terms.[21] Its regulation in relation to the company takes place in a grant agreement. In the latter case, on the other hand, the medical institution and the company enter into cooperation via a cooperation agreement, in which the shared performance of the study is regulated. If the medical facility is a public institution, it is also referred to as a public-private partnership.[22] In contrast to the activity as a contract-research organization, medical institutions in these two cases of funding by a company or through cooperative collaboration are not necessarily regarded as market participants within the meaning of EU laws on state aid and competition law. The new EU Clinical Trial Regulation 536/2014, which will finally be applied at the beginning of 2022, will also cover cases of cooperative sponsorship between a company and a medical institution.
In the end, a rough classification has to be made that differentiates between contract-research organization activity, independent conduct of research, and cooperative research. A very important differentiating criterion is who is responsible for carrying out the study. In practice, a rough distinction can thus be made between three predominantly applicable forms of contract: the grant agreement, the research agreement and the cooperation agreement. The tension between these two will be examined in more detail below. Their differences will be worked out and the essential parts of the agreement will be examined more closely.

2. The Main Types of Contracts

2.1 Grant Agreements / Funding Agreements

Grant agreements are essentially concluded when a funding body supports a research project of the funding recipient with financial and/or material means. The latter include all material means or other investigational drugs, materials under investigation or diagnostic tools. In this case, the recipient, and that seems to be the most important distinction, carries out the study on his own responsibility. If the sponsors are industrial companies or private foundations and/or associations, the terms and conditions of the sponsorship (including the purpose-oriented deductions for a study) are regulated in a sponsorship agreement, whereas in the case of sponsorship by a government agency, the grant of the sponsorship amount is allocated by an act of public law (i.e. notification, administrative act).[23] In such cases, the sponsor does not take responsibility for conducting the study himself, but leaves the legal responsibility as well as the design of the content to the medical facility. In general, it should be understandable that the person, who is legally liable and responsible should also bear the fruits of conducting the study. So the person who bears the responsibility should also own the raw data, results and IP rights. Conversely, the regulations thus show who owns the raw data, the results, and the IP rights, i.e. who bears the responsibility. In return, the recipient typically agrees to prepare interim or final reports (collectively, a "report"), which are then delivered to the funding body and used by industrial funding bodies for marketing purposes in sales or as an auxiliary document for market expansion.[24]
Especially in the case of an IIS/IIT in the field of drug and medical device studies, the support from an industrial company usually consists not only of financial support, but also, above all, of providing the test equipment (e.g. the drug properly labeled for the study). Although there is also a research privilege in Germany for drugs that are already on the market (Section 11 no. 2 of the Patent Act) [25, 26], the medical institution is often unable to obtain or manufacture enough test equipment/medium itself, including the comparative products or placebos, at a low cost. In this case, the funding body produces the drugs or medical devices with specific labeling for the study. It should be noted here that a provision for this in the grant agreement alone is not enough. Instead, in the case of a drug study, a separate drug manufacturing agreement/contract manufacturing agreement according to the German Drug and Drug Substance Act (AMWHV) must be concluded between a medical institution as the sponsor/overall responsible party and a funding body as the manufacturer. Sometimes, however, the legal entity running the production is not the same as the one sponsoring the study. This must be taken into account when drafting a contract. Contract drafting becomes even more complex if the test medication is to be distributed to different centers in different countries and/or if it is not to be done by the medical facility but by the funding body. Thus, the Funding Body acts, on the one hand, as the Sponsor and, on the other hand, as the Contractor (with respect to the drug manufacturing) of the Recipient.
Further caution is required with this contractual structure: As soon as the funding body is involved in contractual negotiations between the medical institution and its other contractual partners for the implementation of the study or by deciding which added service contracts are to be concluded with which partners, it is no longer a question of funding as such, but rather of contract research. In that case, the funding body itself would gradually assume the role of a de facto sponsor, and a contract research agreement would have to be concluded. The boundary here

is fuzzy and must be considered and examined separately in each particular case.

2.2 Contract Research

Contract research is characterized by the fact that the contractor performs certain research and development services for the client on a subcontract basis and transfers the resulting (intellectual) property, in particular the data and, under certain circumstances, the patentable inventions, exclusively to the client.[27] The contractor may, on the one hand, be obliged to achieve certain development goals and, on the other hand, only be obliged to provide certain research services. In this case, the ordering party is the person primarily responsible for conducting the study, even if this party does not conduct the study (completely) alone or exclusively through another person.

The background to this type of collaboration can be, in one respect, that a company desires certain data and results for commercial use or the approval of a drug and uses a medical institution to conduct the study, which in turn only provides a scientific service. In this case, the company usually finances the entire study, acts as the main responsible party and receives all raw data, results and IP rights collected from the study in return.

This classification has mainly monetary effects because the medical facility becomes a market participant in the contract research market and is, therefore, the sponsor's scientific service provider.[28] As such, sales taxes are compulsorily incurred at the time of settlement [29] (although in the international transfer of funds, the next step may be the application of tax reverse charge procedures). What is more important, however, is that the medical facility in Germany is then subject to the EU aid framework and must present a separate accounting and, as a market participant, must ask for the regular price[30], in order not to grant hidden subsidies or even not to be responsible for the distortion of competition.[31] Without going into details, the remuneration that the company has to pay the medical facility is therefore increased by the fact that overhead costs and a profit mark-up have to be calculated. In contrast, in the case of a pure subsidy, the medical facility may have to bear certain costs as its own contribution.

2.3 Cooperation Agreement

In contrast, however, the contracting parties may also conduct a study jointly and have equal rights. Then a cooperation agreement has to be concluded. In addition to the pure material or financial support, the work is divided among the partners according to their respective specialties. [32] Everyone is doing their part to achieve a common goal[33], e.g. the medical facility recruits the patient data and the company analyzes it. The partners therefore not only provide their services for each other, but also for themselves, because the raw data, results, and IP rights belong to all partners jointly. In furtherance of this goal, each partner contributes its own know-how and (intellectual) property rights and generally grants the other partner corresponding rights of use for the duration and purpose of the study. Know-how is understood to be the totality of practical knowledge gained through experience and experimentation and which is secret, i.e. not generally known and not readily accessible.[34] The exact form of the cooperation also decisively depends on whether this cooperation is also supported by public funds via the medical institution. Public funding can be European or national grants or funding programs from some federal states, the federal government, or the EU (e.g. EU funding programs such as Horizon 2020).[35] Beneficiaries can be each partner individually, only one partner or both partners together. Such combinations are particularly common in the field of basic research. For the company involved, it is then important to deal in detail with the relevant funding conditions in advance, as there are always certain requirements for the exploitation of the results and the IP rights developed during the cooperation. The grant recipient (i.e. the medical facility) is in any case subject to certain provisions and possibly non-negotiable grant conditions. Thus, the grantee may be subject to both the obligations under the cooperation agreement and the conditions of the funding body.

In this context, it should be noted that, due to cooperation for a specific purpose, a company is already legally created in accordance with German law[36], which triggers certain legal consequences. For example, this means that each contractual partner is not only liable for its own mistakes, but also for the mistakes of the other contractual partner. This cannot be completely prevented by the contracting parties, but can be mitigated to one degree or another by contractual provisions.

Special features arise if the collaboration is intended to conduct drug or medical device studies. The applicable legal regulations (currently) require that a single natural or legal person be named as the sponsor (Article 2 No. 14 Regulation (EU) No 536/2014, Article 2 No. 49 Regulation (EU) 2017/745, 1.53 ICH-GCP). This sponsor bears, at least externally, the criminal, civil, and regulatory responsibility for carrying out the study. This concept stands in the way of equal cooperation. In this case, therefore, one contractual partner must always bear more external responsibility.

In the light of the above, it should be noted that it is essential for drafting a contract to clear up in advance who will ultimately be responsible for carrying out the study. It is often difficult to determine at what level of responsibility which form of cooperation comes into consideration. As a rule, the one who is responsible for the implementation is the primary responsible person. The one who exercises control over the processes also has to take responsibility. The classification of the type of cooperation finally takes a definite shape on the basis of a few concrete questions, which will be dealt with below. The actual will of the parties is manifested in the concrete form of the agreement.

3. Essential elements of a contract

For this differentiation, it is primarily the provisions on results, inventions, and publications (copyrights) that are important.

3.1. Results

Essential parts of the contract are regulations on the allocation of the objects and goods and their rights that are brought into the study and those that arise from the study. The starting point is the results of the study. In principle, this includes all research and development results obtained from the implementation of the study, including the raw data on which the results are based, including photos, signed declarations of consent and their data carriers, and all statements, documents, reports, and presentations

generated as part of the study.[37] From our point of view, this precise definition is important in order to be able to differentiate the results and their legal treatment from the IP rights developed from the results.

In the context of clinical trials, raw data is basically those data or photos that are introduced into the study database from the source data[38], i.e. primarily from the patient/medical record. This is usually done by first entering the medical assessments made during a medical round into the patient record/medical record and then by transferring them from this so-called source data to a study file or a study database with the help of so-called Case Report Forms (CRF). On the basis of the data and/or photos transmitted via CRF, a raw database of the study is then created, analysed, and the results of which are later summarized in the clinical study report for submission to the authorities. In addition, scientific publications are based on the results. The Clinical Study Report must not be equated with a scientific publication; according to the German classification system, only the latter is a copyrighted work in the context of the Copyright Law.[39]

The essential feature of a grant agreement is that the (ownership) rights to the results and the rights to the source data remain with the Executive Sponsor/overall responsible party, namely with the grant recipient (the person mainly responsible), and that the funding body is granted at most a simple, non-transferable right to use these results, which may be unlimited in time and place, but is mostly limited to the purpose of reviewing the conclusions of the interim and final reports.

In addition, once the results have been published in a scientific publication by the funding recipient, the funding body will want to use them for its own promotional purposes. The same applies in the context of contract research, only here the owner of the rights is the company carrying out the study as a sponsor.[40] Here it is then contractually regulated that the results remain the sole property of the primary responsible party. The background to this is that the company carrying out the study will generally be obliged to submit this data to the approval authorities (especially for drugs and medical devices), but also to the supervisory authorities responsible for the study (especially for drugs and medical devices) in the event of commercialization. By contrast, in the context of contract research, the rights to the source data must remain with the medical institution if it is about patient data. An example of this is informed consent. On the one hand, this is an essential prerequisite for medical intervention and must therefore remain in the patient's file so that the medical institution can prove in a case of damage that the patient consented to the treatment within the framework of a study,[41] but on the other hand, it is a prerequisite for the proper conduct of the study (especially in the case of medicinal products and medical devices) and must therefore be submitted by the company placing the product on the market (usually the former sponsor) in a corresponding approval procedure for the medicinal product.

In contrast to the grant agreement, in the case of contract research, the dispositive power over the data belonging to the medical institution is therefore usually different, i.e. the source data does not simultaneously become the property of the sponsor. Instead of this, they remain with the medical institution. Nevertheless, the sponsor must have access to the source data to verify the accuracy of the results found. Therefore, contract research agreements should stipulate that the sponsor with primary responsibility is to receive the raw data and be granted unrestricted rights of use and access to the source data in order to meet its obligations to provide evidence to the authorities and to fulfill its quality assurance obligations.

Then again, the situation is different for scientific cooperation. Here, a distinction must first be made between drug and medical device trials on the one hand, and other research projects on the other hand. In the case of trials according to the Medicinal Products Act and the Medical Devices Act, it should be noted that basically the sponsor must own the results and must therefore be granted an unrestricted right of access as mentioned above under contract research (all of the aforesaid is in principle applicable here as well). Even when conducting a drug/medical device clinical trial, the partners still have to agree on a sponsor as the overall responsible party, which prevents the applicability of true cooperation (see above). Such cooperation, in our opinion, is currently only possible if the various partners are independent sponsors of very similar, comparable clinical trials that take place in different legal systems, e.g. Europe, USA, China, and these various sponsors then pool their results in order to obtain a global data situation. This seems reasonable, especially if these trials are conducted by university partners in the context of (i) basic research or (ii) if the (rare) diseases studied are financially uninteresting for the companies involved.

If, on the other hand, it is cooperation within the framework of other research projects (e.g. basic research, animal studies), the cooperative conducting of the trial is much more likely to be possible. The partners then only have to clarify in the first step whether they want to appear together externally or not. If they work together outside of the lab, the collaboration becomes legally liable for the research. If, on the other hand, one partner works on its own behalf without the ability to represent the other partner externally, only the respective partners themselves act externally in relation to their own subcontractors or patients. In both cases, the cooperation agreement is required to regulate the exchange of information and the mutual performance obligations between the partners. Since cooperation is primarily determined by the characteristics of the actual division of labour [42], ownership of results only arises as joint ownership, so that the partners can also only jointly dispose of the rights to the results. A right of use should be provided if the results will be used after the trial is completed. However, it is preferable for the partners to clarify this in a separate agreement.

3.2. IP rights

As mentioned before, in our view, all results and raw data fall under the regulatory scope of results. In contrast to ownership as an absolute right to a physical item (material property), IP rights (from Intellectual Property Law) constitute an absolute right to an intangible good (intellectual property) [43], such as a patentable invention, a trademark, a database, developed software, or a design. Inventions (for example, e.g. in the composition of an active substance or a certain procedure) and scientific publications are particularly relevant in the context of research and development cooperation.

3.2.a. Inventions

When drafting a contract, it must be determined whether the IP rights requiring protection already existed before the research study was carried out (so-called pre-existing rights/background) or whether they arise from the research study or in the context of the research work (so-called new rights/foreground).[44] The distinction is always important if the IP rights of one party are used by the other party in the context of the study or should be used beyond the study.

3.2.a.aa. Pre-existing rights (Background IP)

Pre-existing rights, of course, are always the property of the possessor. This is also not affected by the conduct of the research study. However, the form in which the research is conducted has a significant impact on the contract's regulatory density. A manufacturer sometimes provides a (medical) product or a drug as part of a grant agreement. Because the rights to this do not belong to the grant recipient/sponsor conducting the study (i.e. the medical facility), the grant agreement must clearly establish the right of use of the medical facility for this product within the scope of the study.

In the context of contract research, this is not necessary because the sponsor (here: the company) makes the products available for carrying out the study within the framework of the test center contract, and so this is already part of its main obligation. The transfer of the test equipment/test product for carrying out tests does not require any special regulations concerning its use. The situation changes if the sponsor provides the medical facility with other devices in addition to the test equipment/test product, such as EKGs, refrigerators, thermometers, and other devices that are meant to support the medical facility's activities as part of the research. In the vast majority of cases, however, this will be done by means of a separate rental agreement or a supplementary rental clause, which then makes a separate provision for the pre-existing rights non-topical.

In a cooperation agreement, on the other hand, it is essential to include a clause on the pre-existing rights to be brought into the cooperation by the respective partners. Since the aim here is to work jointly on the research questions, and the respective sub-projects always have to access the other sub-projects and are inspired by them, there is almost inevitably a constant mixing and mutual use of the rights introduced in each case. Without a correspondingly clear regulation, the mutual use of pre-existing rights would be associated with considerable legal risks. Such clauses help to ensure that the partners can consult with their societies/departments specializing in collective management of copyright and related rights in advance to determine whether there are any obstacles to use in the research study in the form of already existing license agreements. Clear regulations also aid in the cooperative resolution of later disputes, particularly when a pre-existing right is improved or further developed by a partner other than the holder.

3.2.a.bb. New Rights (Foreground IP)

A regulation on the acquisition of new rights, in contrast to the regulations on pre-existing rights, makes sense in every contractual framework discussed here. However, there are important differences in terms of regulatory content depending on the desired form of cooperation.

In the context of grant agreements, it will usually be the case that the patentable inventions belong solely to the grant recipient, who, after all, bears the sole risk of carrying out the study. Thus, constellations in which the new rights do not belong to the conducting medical institution are likely to indicate that the funding body is in fact regarded as the responsible party and thus as the sponsor. In this situation, the medical institution does not perform the scientific study for its own benefit, as that would involve obtaining the results of studies as well, but rather for the benefit of the financing body receiving the new rights. If these new rights were transferred to the manufacture of the test equipment/test product without proper compensation, the latter would become the de facto sponsor. This is due to the fact that it would be a classic example of contract research in drug and medical device clinical trials. An exception to this conclusion appears to be possible only if the new rights cover the specific material resources that the funding body made available to the funding recipient for the purpose of conducting the scientific study, but the study is not about testing these specific material resources, but, for example, about testing a method. The material resources brought in are, therefore, being used to develop a different scientific problem rather than test equipment/test goods. If improvements or extensions of the material resources are then made in this context, it should be possible to transfer these to the funding body without then making the latter the overall responsible party.

In the case of contract research, the main responsible person owns any patentable innovations created during the study, and the contractor will transfer all rights to these inventions to the main responsible person who accepts the assignment.[45] In German law, there is a globally unique provision in this respect, the Employee Inventions Act (ArbnErfG).[46] According to this, the employee who created the invention should be entitled to the invention's rights. The employer may acquire them for corresponding compensation.[47] In the case of contract research, it is probably the rule that the invention originates from the contractor's employees. Therefore, it is recommended that an arrangement be made in which the statutory employer's rights and obligations under the Employee Inventions Act (ArbnErfG) are assigned to the main person responsible in advance, or, in any case, the sponsor is granted a preferential right to acquire, and the employee agrees in advance to acquire the inventions from his or her subordinate employee in exchange for compensation. At the very least, a non-commercial right of use for research and teaching should be granted to the medical institution.[48]

In this light, it makes sense to define in advance what constitutes an individual invention and what constitutes a joint invention in the context of cooperative collaboration, including the respective regulations on how these are to be acquired, what constitutes the process for compensation with the other partners, whether option rights are to be granted, and so on. The invention rights are to be granted on the basis of a patent application. Furthermore, if one partner does not intend to file a patent application for the invention, a mechanism must be established for the other partner to obtain the right to the invention.[49] In this case, the duty to inform the other partner and the necessity of concluding a separate transfer agreement should be regulated. The outsourcing to a separate contract also makes sense because the necessary contractual discussions

and negotiations can be conducted much more easily on a concrete subject than abstractly for all possible cases in the cooperation contract. This should also make the contractual negotiations of the cooperation agreement much easier.
However, it must also be ensured in a cooperation agreement that the joint inventions become known to the partners and that the cooperation of the partners is required for effective use and commercialization. Against this background, the respective partner located in Germany must also be obliged to comply with the provisions of the Employee Inventions Act.

3.2.b. (Interim) reports and scientific publications

At least at the end of the study, but also sometimes in between, the (interim) results of the study are evaluated from time to time. This is done by means of interim or final reports (jointly called "report") and at the end there is a presentation of the results to the (expert community) public by means of publication, seminar papers, etc. The report is thus primarily an internal means of communication between the contracting parties[50], whereas the publication is a detailed published work on the research project that meets scientific requirements. Only the latter is likely to be considered a work in the sense of copyright law and generate copyrights.[51]
The grant recipient should normally be required to produce and submit a report to the funding body as part of the funding agreement. The grant recipient, on the other hand, is responsible for the eventual publication of the results (or the scientist in charge of the study). Since the property rights to the results and source data remain with the grant recipient, the funding body may only use the report for internal purposes. Foundations and other private funding bodies may request that the findings and/or reports be made public on their own initiative. However, to avoid jeopardizing the funding recipient's scientific publication, which could include dissertations or postdoctoral theses, care should be taken to ensure that such independent publication rights are only granted after the publication has been submitted, or better yet, after it has been published. In this case, a contractual term stating that the funding body must keep the content of the report confidential until the grant recipient releases it is useful.
In the context of contract research, it depends on whether the contractor, in addition to the sponsor, intends to publish the findings (results). Since the sponsor is the principal author of the study, he should generally be given priority, especially because this also allows the sponsor to control the flow of information about the study results and thus effectively exercise his ownership rights over them.
Nevertheless, scientific staff of a medical institution in Germany will always have the right to publish their scientific work, according to Art. 5 III of the Basic Law in connection with Section 242 of the Civil Code.[52] Here, therefore, the interest of the sponsor in the effective exercise of his property rights collides with the publication interest of the participating scientist of the medical institution. This conflict is usually resolved by including a provision in which the contractor grants the mainly responsible person (party) a full right of use of the copyrightable results and the contractor agrees that the customer publishes the results together with the scientist of the medical institution. In the case that there is no publication or no timely co-publishing, the medical institution or the participating scientist will be permitted to publish the study data collected from them separately. In practice, based on the copyright established by the publication, a period of 12 to 18 months after the data base lock has crystallized as the term for the scientist to wait. Furthermore, the contractor should be awarded a non-commercial right of use, at least for research and educational purposes. This should be at least as far as the publishing houses where the publication is published allow. This right of use, however, should be provided with the condition that the results remain confidential until the customer has publicized them. Mere communication on the intranet of an institution, on the other hand, is permitted without any problems.
Research cooperation usually involves joint publication.[53] Depending on how independent the subprojects are, however, individual publications should also be allowed. This is all the more important the more scientific the nature of cooperation is. It is also advisable to regulate the procedure to be followed if only one partner intends to publish the results alone. Two things are essential. Firstly, the other partner must be granted a right of use after publication, at least for non-commercial purposes. On the other hand, the non-publishing party can request deletions or a limited postponement if the planned publication is about their own IP rights or their registration.
In all cases, however, an appropriate procedure should be established, according to which the parties/partners must inform each other accordingly, even in the case of individual publications. It will probably not be possible to establish a strict requirement for the consent of the non-publishing partner/party to an individual publication in Germany with reference to Art. 5 III of the Basic Law in conjunction with Section 242 of the German Civil Code (BGB), but there may be a right of review for the other party and a temporary request to defer the publication in order to protect one's own intellectual property rights.

4. Conclusion

The aim of the above presentation was to show that the implementation of a research project can take place in different ways, resulting in different legal implications. There are roughly three distinctions here: (1) research support, (2) contract research, and (3) cooperation. All three manifest themselves primarily in different rules on (a) results and (b) IP rights, the latter including inventions and publications. Of course, the three types of contracts do not only consist of these clauses, but the structure of the contracts and the scope of the regulations in the other areas are similar. For example, it always needs a heading and a signature page, there must always be something on the subject matter of the contract, and there is a need for rules regarding confidentiality, liability, termination, jurisdiction, etc. As important as these rules are in detail, we've found that discussions between companies and medical institutions regarding the type of research funding that's truly needed here have primarily revolved around the issues raised in this essay.

5. Acknowledgments

The authors would like to thank Mr Maik Schlinker and Ms Madita Bienias for reviewing and editing work for the article.

6. Declaration of conflicting interests

The author declares no conflicts of interest with respect to the research, authorship, and/or publication of this manuscript.

7. Funding

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

8. References

1. §4 para. 23 sentence 1 AMG. https://www.gesetze-im-internet.de/amg_1976/; access on 27. October 2021.
2. ICH-GCP e6 1.12. https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e6-r1-guideline-good-clinical-practice_en.pdf; access on 27 October 2021.
3. Deutsch E. Der Beitrag des Rechts zur klinischen Forschung in der Medizin, Neue Juristische Wochenschrift, 1995, 3019-3024.
4. Laufs AL, Katzenmeier C, Lipp V. Arztrecht. Verlag C.H. Beck oHG, München, Germany, 2021, Chapter XIII. marginal no. 1.
5. Dieners P. Handbuch Compliance im Gesundheitswesen. Verlag C.H. Beck oHG, München, Germany, 2010, B. marginal no. 15.
6. §4 para. 24 AMG. https://www.gesetze-im-internet.de/amg_1976/; access on 27. October 2021.
7. §25 MPDG. https://www.gesetze-im-internet.de/mpdg/; access on 27 October 2021
8. Articel 62 para 2 sentence 1 Regulation (EU) 2017/745. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745; access on 27. October 2021.
9. Kügel/Müller/Hoffmann, Arzneimittelgesetz, AMG §40 marginal no. 22.
10. Dienemann S, Wachenhausen H. Alles neu, macht die EU – Die Verordnung über klinische Prüfungen und ihre Auswirkungen auf das deutsche Recht. PharmR, 2014, 10: 452 - 453.
11. §15 para. 1, 2 MBO-Ä. Deutsches Ärzteblatt 2021, 23: A1-A9.
12. §67 para. 6 AMG. https://www.gesetze-im-internet.de/amg_1976/; access on 27. October 2021.
13. Meier A, von Czettritz P, Gabriel M, Kaufmann, M. Pharmarecht, Verlag C.H. Beck oHG, München, Germany, 2018, §3 marginal no. 16.
14. Bischoff C, Wiencke J. Zeitschrift für Datenschutz 2019, 1: 8 -13.
15. Dieners P. Handbuch Compliance im Gesundheitswesen. Verlag C.H. Beck oHG, München, Germany, 2010, B. marginal no. 17.
16. Dieners P. Handbuch Compliance im Gesundheitswesen. Verlag C.H. Beck oHG, München, Germany, 2010, §4 marginal no. 129.
17. Hänlein A, Schuler R. Sozialgesetzbuch V. Nomos, Germany. 2016, §35c marginal no. 13.
18. Spickhoff A. Medizinrecht, Verlag C.H. Beck oHG, München, Germany, 2018, MPG §1 marginal no. 2.
19. Müller-Glöge R, Preis Ulrich, Schmidt I. Erfurter Kommentar zum Arbeitsrecht, Verlag C.H. Beck oHG, München, Germany, 2021, AentG §14 marginal no. 3.
20. Stief M, Bromm B. Vertragshandbuch Pharma und Life Sciences. Verlag C.H. Beck oHG, München, Germany, 2021, 1. Chapter VI C 1. marginal no. 8.
21. Spickhoff A. Medizinrecht, Verlag C.H. Beck oHG, München, Germany, 2018, AMG §40 marginal no. 24.
22. Huster S, Kaltenborn M. Krankenhausrecht. Verlag C.H. Beck oHG, München, Germany, 2017, §1 marginal no. 33.
23. Fehling M, Kastner B, Strömer R. Verwaltungsrecht. Nomos Verlagsgesellschaft, Baden-Baden, Germany, 2021, §35 Rn. 85.
24. https://www.dfg.de/foerderung/programme/einzelfoerderung/klinische_studien/formulare_merkblaetter/; accessed on 21 June, 2021.
25. Patentrechtliches Versuchsprivileg – Klinische Versuche II. Neue Juristische Wochenschrift, 1997, 46: 3092-3096. (BGHZ 135, 217)
26. Benkard G. Patentgesetz. Verlag C.H. Beck oHG, München, Germany, 2015, §11 marginal no. 8.
27. Stief M, Bromm B. Vertragshandbuch Pharma und Life Sciences. Verlag C.H. Beck oHG, München, Germany, 2021, 1. Chapter VI A.
28. Rechtsgrundlage für die Drittmittelforschung ist etwa §25 HRG.
29. Stief M, Bromm B. Vertragshandbuch Pharma und Life Sciences. Verlag C.H. Beck oHG, München, Germany, 2021, 1. Chapter VI B. marginal no. 92.
30. Huber S, Prikoszovits J. Universitäre Drittmittelforschung und EG-Beihilfenrecht. Europäische Zeitschrift für Wirtschaftsrecht, 2008, 6: 171-174.
31. Art. 107 AEUV. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12012E/TXT:de:PDF; access on 27. October 2021.
32. Dieners P. Handbuch Compliance im Gesundheitswesen. Verlag C.H. Beck oHG, München, Germany, 2010, §20 marginal no. 8.
33. Beck´sche Online -Formulare Vertrag. Verlag C.H. Beck oHG, München, Germany, 2021, 12.4 Kooperationsvertrag, notation 2.
34. Stief M, Bromm B. Vertragshandbuch Pharma und Life Sciences. Verlag C.H. Beck oHG, München, Germany, 2021, 0. Chapter C. marginal no. 21.
35. https://ec.europa.eu/programmes/horizon2020/; accessed on 21. June2021
36. Forster J. Die Haftung des neuen Co-Sponsors. PharmR 2020, 11: 657-662.
37. Bekanntmachung eines Konsens-Dokuments der Bund-Länder-Arbeitsgruppe Gute Laborpraxis (GLP) zum Thema „Gute Laborpraxis (GLP) und Datenverarbeitung, p. 5, https://www.bfr.bund.de/de/glp_schriften-481.html; access on 21. June, 2021.
38. Definition Source Data: ICP ICH e6 1.51. https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e6-r1-guideline-good-clinical-practice_en.pdf; access on 27 October 2021.
39. On the concept of (the) work. Dreier T, Schulze G, Specht L. Urheberrechtsgesetz, Kommentar, §2 marginal no. 6: The protectability of the work only exists insofar as it is a personal intellectual creation.
40. Dieners P. Handbuch Compliance im Gesundheitswesen. Verlag C.H. Beck oHG, München, Germany, 2010, §20 marginal no. 21.
41. §§630d, 630f, 630h para 2 S. 1 BGB. https://www.gesetze-im-internet.de/bgb/; access on 28. October 2021.

42. Stief M, Bromm B. Vertragshandbuch Pharma und Life Sciences. Verlag C.H. Beck oHG, München, Germany, 2021, 1. Chapter VI B.1. marginal no. 58.
43. BeckOK BGB, 58. Ed. 1.5.2021, § 903 Rn 10.
44. Stief M, Bromm B. Vertragshandbuch Pharma und Life Sciences. Verlag C.H. Beck oHG, München, Germany, 2021, 1 Chapter VI C. Rn. 20.
45. Stief M, Bromm B. Vertragshandbuch Pharma und Life Sciences. Verlag C.H. Beck oHG, München, Germany, 2021, 1 Chapter VI C. Rn. 22.
46. For more details on the procedure, see § 5 para. 1 sentence 1 and § 6 para. 1 ArbNErfG: The employee has the duty to disclose the invention to the employer. The employer may decide whether to claim the invention. https://www.gesetze-im-internet.de/arbnerfg/; access on 27. October 2021.
47. § 9 para 1 ArbNErfG. https://www.gesetze-im-internet.de/arbnerfg/; access on 27. October 2021.
48. Stief M, Bromm B. Vertragshandbuch Pharma und Life Sciences. Verlag C.H. Beck oHG, München, Germany, 2021, 1 Chapter VI C. Rn. 25.
49. More details on the patent agreement between sponsor and examiner cf. Stief M, Bromm B. Vertragshandbuch Pharma und Life Sciences. Verlag C.H. Beck oHG, München, Germany, 2021, 1 Chapter VI B 2. marginal no. 32 ff.
50. Further to the purpose of the reports, cf. Milbradt/Stief in: Stief M, Bromm B. Vertragshandbuch Pharma und Life Sciences. Verlag C.H. Beck oHG, München, Germany, 2021, 1. Chapter VI C 1. marginal no. 39.
51. According to § 2 para. 2 UrhG, works are only personal intellectual creations.
52. Stief M, Bromm B. Vertragshandbuch Pharma und Life Sciences. Verlag C.H. Beck oHG, München, Germany, 2021, 1. Chapter VI C 1. marginal no. 38.
53. Stief M, Bromm B. Vertragshandbuch Pharma und Life Sciences. Verlag C.H. Beck oHG, München, Germany, 2021, 1. Chapter VI C 2. marginal no. 90.