



Terms and Conditions for Service Agreements of CTU Bern, Department of Clinical Research

Version: 09 / 23.04.2024

These general Terms and Conditions for Service Agreements of CTU (hereinafter "TCs") govern together with the corresponding confirmation (hereinafter "Confirmation") the contractual relations between a partner (hereinafter "Partner") and Department of Department of Clinical Research, University of Bern, CTU Bern; Mittelstrasse 43, 3012 Bern (hereinafter "CTU") for the support of Partner by CTU in the performance of a project (hereinafter "Project"). By signing the Confirmation, Partner acknowledges and accepts the inclusion of the TCs. The agreement (hereinafter "Agreement") is concluded with the signature of the Confirmation by CTU which has to be the last signature.

1. General

1.1 The Agreement consists of the Confirmation and the TCs and constitute the entire and only contractual relations between the parties relating to the Project and the tasks, and all prior negotiations, representations, agreements, and understandings are superseded hereby.

1.2 In case of any conflicts between the Confirmation and the TCs, the Confirmation shall prevail.

2. Obligations /Aims

2.1 CTU agrees to use its good faith efforts to conduct its tasks within the Project as set forth in the Confirmation ("Tasks") signed by both parties as an independent contractor, in accordance with CTU policy, applicable laws and regulations and the protocol, in its current version and as provided for by Partner, if applicable. If appropriate, Partner assumes all obligations as the sponsor of the Project according to the Swiss Human Research Act of 30. September 2011 and related ordinances and according to applicable laws and regulations.

2.2 Partner agrees to support CTU in order to conduct the Tasks within the Project by paying a contribution according to Article 3 as well as providing all necessary data and information as required to perform the Tasks.

2.3 For the sake of clarity, CTU shall only perform the Tasks as set out in the Confirmation and have no obligation to perform further work except additional specification of activities and their remuneration agreed upon written amendment to the Confirmation. Specifically, any additional expenses incurred by CTU in the course of inspections or audits are not covered by this Service Agreement and will be additionally reimbursed to CTU by Partner, unless such expenses are explicitly covered by the agreed cost estimate.

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3. Contribution

As support for performing the Tasks within the Project, CTU shall be paid in accordance with the agreed costing. Costs will be invoiced quarterly in CHF and for actual working hours performed, which may deviate from the estimate of required hours made in the costing. Any transfer fees shall be paid by the invoice recipient. Without prejudice to the aforesaid, each party shall bear its own costs, arising in the conduct of the Project.

The payments shall be made to the following account of CTU:

Finanzverwaltung des Kts. Bern, 3011 Bern
Postkonto in Bern/CH: 30-406-7
Clearing: 09000
Swift: POFICHBE (Swiss Post, PostFinance, CH-3030 Bern)
IBAN elektronisch: CH9209000000300004067
IBAN Papierform: IBAN CH 92 0900 0000 3000 0406 7
Vermerk: 1535 Kredit: 34-890
MWSt.: CH-115.2501.351

The calculation of the budget depends on the hourly rates of CTU. The hourly rates are subject to annual adaptation.

Meal allowances are invoiced as lump sum in accordance with the terms of University of Bern.

Important information on your invoice:

The example invoice below shows the details that are disclosed on the standard invoices of CTU Bern. If more details are required on the invoice, CTU needs to be informed in advance. No more detailed information can be provided retrospectively, e.g. when invoices were sent out.

Pos.	Bezeichnung	Anzahl	Einheit	Preis	MWST%	TOTAL CHF
1	CTU Monitoring	12	-	150.00	0.00	1800.00
2	CTU Statistics	12	-	150.00	0.00	1800.00

4. Term

4.1 The term of this Agreement shall begin on the date of signature of the Confirmation by CTU and shall continue until all responsibilities are completed.

4.2 CTU and Partner may terminate the Agreement at any time in the event of untoward side effects or other medical risks occurring during the Project.

4.3 A party may terminate the Agreement immediately if the other party breaches or is in default of any obligation agreed upon in the Confirmation or of the included TCs of CTU and which has not been cured within thirty (30) days after receiving written notice of such breach or default.

4.4 Partner shall provide CTU with all information and documents required for CTU to perform its agreed Tasks within the Project. This may include, but is not limited to:

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- ethics committee and regulatory authority approval (unless services provided by CTU were completed prior to EC approval),
- first participant enrolled,
- recruitment stopped prematurely or temporarily interrupted,
- last participant visit performed,
- data cleaning completed,
- any new protocol version implemented during the course of the Project,
- changes in study staff requiring access to the clinical data management system.

4.5 CTU reserves the right to replace or shut down the clinical data management systems if deemed necessary. CTU will inform all involved parties 6 months ahead of the replace or shut down. All costs relating to a potential migration of the database to a different clinical data management system have to be borne by the Partner.

4.6 CTU reserves the right to update the clinical data management systems at any time, which may lead to a few downtimes a year. During the specified time the clinical data management system is not available (including randomization, surveys or any other functionality).

4.7 CTU is committed to provide services in due time to meet anticipated project timelines. To allow appropriate planning Partner is asked to inform CTU in good time about the anticipated date/time frame of the contracted services (also refer to CTU Bern Service Timelines as published on the CTU homepage: Services/Timelines, Costs).

4.8 CTU is available for support and requests during normal office hours (Monday to Friday from 9-17h, best via email). CTU does not offer services during nighttime, weekends or public holidays.

4.9 Partner acknowledges all terms listed in Appendix I related to data management and clinical data management systems (so-called Full Service or REDCap Light).

5. Liability

Partner shall indemnify and hold harmless CTU, its regents, officers, agents, employees from any and all liabilities, losses, damages, claims, and expenses in connection with any claim or lawsuit brought against CTU by a third party as a result of i) the performance of the Tasks as set out in the Confirmation by CTU or ii) from the use by Partner of the results of the Study Project iii) from a possible misuse of the local super user rights provided to Partner on the study database (e.g. in case data/database needs to be corrected/restored due to misconduct by Partner all costs have to be beard by Partner); provided, however, that Partner shall not hold CTU harmless from liability resulting from willful misconduct or gross negligence of CTU, its agents, or employees. Furthermore, Partner shall have a recourse claim against CTU for the cover of damages resulting from willful misconduct or gross negligence of CTU, its agents, or employees.

6. Warranties

6.1 CTU agrees to properly perform, to the best of its knowledge and taking into account the current state of the art, the Tasks assumed by it under this Agreement.

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6.2 CTU makes no warranties, expressed or implied, as to any matter whatsoever, including and without limitation, the accuracy of the results of the Tasks or any invention(s) or product(s), whether tangible or intangible, conceived, discovered, or developed under this Agreement; or the merchantability, or the fitness for a particular purpose of the results of the Tasks or for any such invention or product.

7. Intellectual property

7.1 Partner shall retain full ownership of the results arising from performing work governed by the Agreement, provided, however, that CTU shall be entitled to use the results for internal and non-commercial purposes.

7.2 All know-how, processes, procedures, methods, and developments including but not limited to scripts provided for the use of data preparation, validation, and analysis, which are solely developed and used by CTU to perform the Tasks and all intellectual property related thereto, whether created before, during, or after the Project, shall be owned solely by CTU, (hereinafter "Know-how"), and, if made available to Partner, Partner agrees to acknowledge the use of Know-how or consider co-authorship in any publication Know-how is used for (altered or unaltered).

7.3 Partner agrees and acknowledges that CTU may collaborate with and uses software/database solutions of Webspirit Systems GmbH, Böttgerstrasse 2/3, D-89231 Neu-Ulm in the performance of the tasks hereunder.

8. Publication and confidentiality

8.1 Partner shall have the right, consistent with internationally accepted academic standards, to present and publish results of the work governed by the Agreement. Authorship will be governed by the Uniform Requirements issued by the International Committee of Medical Editors (ICMJE).

8.2 Each party shall hold in confidence for three (3) years after the termination of the Agreement any confidential information identified as confidential and obtained from the other party during the course of this Project (hereinafter "Confidential Information"). Nothing herein, however, shall prevent the parties from using any information generated hereunder for ordinary research and educational purposes. Confidential Information may be disclosed to the extent required by information-, data protection- and archive legislation, and for purposes of trial participant care.

8.3 The parties agree that CTU's use and disclosure of study participant health and medical information is subject to compliance with applicable state and federal data privacy laws. The parties, therefore, agree to take all reasonable steps to protect the confidentiality of any study participant health and medical information that they have access to and to comply with applicable laws.

8.4 Partner acknowledges, that CTU aims at being independent of financially driven biases and therefore maintains a funding list on CTU's website, where the Project will be included, if relevant.

8.5 All works such as templates, work instructions, and user manuals that are created and authored by CTU are under the Creative Commons Attribution 4.0 International License. Partner may reproduce, distribute and make publicly accessible the work. Partner must include the name of CTU Bern, the title of the work, its sources, and this license CC-BY 4.0. To view a copy of this license, visit <http://creativecommons.org/licenses/by/4.0/>.

9. Governing law and Place of Jurisdiction

The Confirmation and these TCs of CTU shall be governed by the laws of Switzerland. Place of jurisdiction shall be Bern, Switzerland.

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Appendix I: Terms related to data management and clinical data management system (CDMS)

A Terms for so-called Full Service projects (CTU sets up study database):

- Partner shall approve final eCRFs/database to confirm that CTU has implemented the study database according to Partner's specifications and to be in line with approved protocol version before database is released for data entry.
- Partner is responsible for submitting any eCRF/database changes to the appropriate authorities.
- In case a database set up by CTU needs to be modified after a software update in order to ensure correct operation, the caused costs will be charged to the customer.

Partner is informed that CTU generally does not charge any license costs or server fees. If a study is conducted according to protocol or as agreed on in regular communication between the Partner and CTU, no fees will be applied. Nonetheless CTU reserves the right to check the project state and charge a fee in case database locking or archiving is postponed with no reason communicated by the Partner and server space cannot be freed in due time (this also includes the interruption of data collection). The fee of the amount of CHF 1500 will cover the database server costs for another 4 years.“

B Terms for so-called REDCap Light projects (Partner sets up own study database):

- CTU creates a REDCap project and provides template eCRFs, standard roles, user manual, training slides. CTU is responsible for creating users. Partner is responsible for own study database, including: setup of eCRFs/database, testing thereof and deployment; training; user and role management; any changes to the eCRFs/database; closing, locking and archiving (i.e. Partner is responsible to request full audit trail export from CTU); appropriate documentation.
- Partner is requested to inform CTU in case a REDCap super user changes or leaves.
- Partner acknowledges that CTU does not recommend REDCap Light for the following scenarios: (i) blinded studies; (ii) studies exceeding the limit of 15'000 records; (iii) studies exceeding the limit of 5'000 fields.
- CTU takes no responsibility for performance issues and reserves the right to close down a project if it would block the system or services.
- CTU - apart from a requested and agreed review before the first deployment - does not review the database for any further deployments, if not specifically requested at the moment the 'change to production' request comes in.
- Partner is responsible for ensuring that the project specific functionalities (e.g. branching logics, calculations) are still working correctly after a software update.
- Partner is informed that CTU does not charge any license costs or server fees for the first 4 years after creation of the database. After the first 4 years the Partner has the possibility to either get in contact with CTU and prolong the database for another 4 years for the service costs of CHF 1000 (and if applicable an updated contract amendment) or CTU will take the liberty to set the project status to 'complete' after 3 months after being contacted. Partner is informed that CTU will delete the database 2 years after setting status to 'complete'.

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- This service is only provided for members of the Inselspital Bern or University of Bern. If Partner changes the sponsor's institution, Partner is requested to find a successor or to move the database. Alternatively, CTU may decide to convert the project to a so-called Full Service, its decision is entirely at CTU.
- In case Partner uploads document in one of our CDMS: 1) Documents must be coded (if not approved differently by the ethics committee); 2) the maximum file size is 20 MB; 3) Partner is responsible to oversee used storage (if not agreed otherwise).

Revision Index

Version	Chapter	Summary of changes
01 / 26.10.2018	---	T&C removed from contract template; standalone document with code MAN_CON_FOR-01
02 / 29.04.2019	---	Code change from MAN_CON_FOR-01 to GS_GEN_REC-01 to align with QMS processes and document codes in use
03 / 30.01.2020	3	Inclusion of “important information for invoice” including example table
04 / 11.08.2020	4.4	New chapter added: database lock after study end
05 / 16.11.2020	4.5	New chapter added: CTU reserves itself the right to replace or shut down Clinical Data Management Systems (CDMS)
06 / 11.02.2021	4.6	New chapter added: obligations of Partner to provide CTU with information and documents required for the performance of the agreed Tasks of CTU
07 / 22.03.2022	4.5	New chapter Software Updates
	4.6	Requirement added: costs relating to a potential migration of the database to different CDMS must be born by customer
08 / 05.10.2023	4.4	Clause removed as internal CTU processes were implemented instead
	4.5 / 4.6	Clauses moved to different location within document (further down or in appendix)
	New 4.6 / 4.7	New clauses implemented on CTU service timelines and office hours
	New 4.8	New clause separating data management terms into REDCap Full and Light service listed in new Appendix I
	Appendix I	Appendix added: definition of terms related to data management services REDCap Full and Light and clinical data management system use
09 / 23.04.2024	2.2	Addition in regards to costing of expenses.
	3	Currency and payer of transfer fees specified
	Appendix I	Adapted billing of possible server fees.