

# Terms and Conditions for Service Agreements of CTU Bern

Version: 07 / 22.03.2022

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 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relating to the Project and the tasks, and all prior negotiations, representations, agreements, and understandings are superseded hereby.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.

## 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 and for actual working hours performed, which may deviate from the estimate of required hours made in the costing. Without prejudice to the aforesaid, each party shall bear its own costs, arising in the conduct of the Project.

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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** Database Lock: Study databases should be closed after study end. To ensure this, the sponsor is required to submit a signed database lock request to CTU. CTU reserves its right to close a study databases hosted by CTU if there has been no activity on data (data entry, data cleaning, querying) for more than one (1) year and if there were at least two unsuccessful attempts to contact the sponsor.

**4.5** Software Updates: If users set up their own study databases (e.g. using CTU Bern REDCap Light Service), they carry the responsibility to verify that the project specific functionalities (e.g. branching

logics, calculations) are still working correctly after a software update. 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.

**4.6** 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 change. All costs relating to a potential migration of the database to a different clinical data management system have to be borne by the customer.

**4.7** 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:

- ethics committee and regulatory authority approval,
- first participant enrolled,
- last participant visit performed,
- any new protocol version implemented during the course of the Project,
- changes in study staff requiring access to the clinical data management system.

In addition, provided the Tasks under this Agreement were not completed prior to ethics committee approval of the Project, Partner shall provide CTU with a copy of the ethics committee approval document.

## **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.

**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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## 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