

OpenClinica Self-Service Subscription Terms and Conditions

Draft click-through terms adapted from the OpenClinica enterprise MSA and Data Protection Agreement

Acceptance method	Customer accepts these Terms by clicking to agree, completing checkout, or otherwise placing an online order for a Self-Service Plan.
Plan model	Online, self-service subscription with standardized entitlements and limited live support/compliance interaction.
Related documents	The applicable online order, plan description, the Data Protection Agreement where applicable, and any mutually executed Business Associate Agreement (if any).

Important for self-service subscribers. Support and compliance services under this plan are delivered primarily through OpenClinica’s self-service resources, documentation, ticketing/workflow portal, standard forms, and asynchronous communications. Access to named support agents or compliance personnel by phone, email, or web is limited and not included except to the extent expressly stated in the purchased plan or separately ordered by OpenClinica.

By clicking “I Agree,” Customer acknowledges that these Terms are intended to be the binding principal agreement for the Self-Service Plan.

1. Agreement Structure and Definitions

These Self-Service Subscription Terms and Conditions (the “Terms”) are entered into between OpenClinica, LLC (“OpenClinica”) and the entity or person identified during the online purchase flow (“Customer”). These Terms become effective on the date Customer accepts them through the online purchase flow or first uses the Self-Service Plan, whichever occurs first (the “Effective Date”).

These Terms govern Customer’s access to and use of the OpenClinica services, documentation, websites, APIs, and related offerings included in the purchased self-service plan (collectively, the “Services”). The online checkout page, subscription summary, pricing page, or similar order confirmation identifying the plan, term, fees, and usage limits is the “Order.” The Order is incorporated into and forms part of these Terms.

To the extent applicable to Customer’s use of the Services, the OpenClinica Data Protection Agreement (“DPA”) is incorporated by reference into these Terms and forms part of the parties’ agreement. If there is a conflict between these Terms and the DPA with respect to processing of Personal Data, the DPA controls for that subject matter.

“Authorized User” means an individual authorized by Customer to use the Services for Customer’s permitted clinical research activities, including Customer personnel, contractors, site personnel, and study participants as applicable to the purchased plan. “Customer Data” means data provided by or on behalf of Customer or its Authorized Users to OpenClinica in connection with the Services. “Usage Data” means technical and usage information relating to Customer’s and its Authorized Users’ use of the Services, including but not limited to, information pertaining to the number and status of Customer Studies, sites, CRFs, event definitions, rules, study subjects, data extracts, and data related to system usage patterns and user load. OpenClinica owns Usage Data.

2. Provision of Services; Self-Service Model

OpenClinica will provide the Services included in the applicable Order during the subscription term. Customer receives a non-exclusive, non-transferable, non-sublicensable, limited right for Customer and its Authorized Users to access and use the Services and the related documentation during the term solely for Customer's permitted clinical research and related administrative purposes.

Customer understands that this subscription is a standardized self-service offering. Unless expressly included in the applicable plan or separately purchased from OpenClinica, the Services do not include dedicated implementation services, custom validation documentation, custom legal or privacy reviews, sponsor-specific compliance consulting, managed study build services, or guaranteed access to support agents or compliance officers by phone, direct email, or video conference.

OpenClinica may require Authorized Users to agree to online user documents, acceptable use notices, or workflow-specific click-through terms in connection with use of specific Services or features.

2.1 Usage Limits for Self-Service Plans

Customer's use of the Services under the applicable Order is subject to the following per-study data usage maximums ("Usage Limits"). OpenClinica may monitor Customer's usage, and if Customer exceeds these Usage Limits, OpenClinica may charge Customer for overages or require Customer to upgrade to a higher plan as provided in Section 5.

The per-study Usage Limits are:

- **Participants:** A maximum of 1,000 active participants per study.
- **Item Data Values:** A maximum of 450,000 total Item Data Values (data points) per study.
- **Study Design Maximums:**
 - 20 events
 - 50 CRFs (Case Report Forms)
 - 3,000 unique items

3. Support and Compliance Services for Self-Service Plans

Support and compliance assistance under the Self-Service Plan will be delivered primarily through OpenClinica's support portal, help center, documentation, self-service workflows, standard templates, knowledge base content, and other generally available asynchronous channels designated by OpenClinica.

Customer acknowledges and agrees that response times, service levels, and available support channels for the Self-Service Plan may differ from OpenClinica's enterprise offerings. Customer's ability to work directly with OpenClinica support agents, project personnel, or compliance officers by phone, direct email, or web is limited and may be unavailable unless expressly stated in the applicable plan or separately purchased.

OpenClinica may, in its discretion, offer limited live interaction for escalations, service recovery, security incidents, or other matters requiring direct engagement, but nothing in these Terms obligates OpenClinica to provide named personnel, scheduled office hours, or bespoke compliance support as part of the Self-Service Plan.

4. Customer Responsibilities and Restrictions

Customer is responsible for: (a) maintaining accurate account, billing, and user information; (b) obtaining and maintaining the internet connectivity, carrier services, devices, and other third-party infrastructure required to access the Services; (c) controlling user credentials and account permissions; and (d) ensuring that Customer and all Authorized Users use the Services in compliance with applicable law and these Terms.

Customer will not, and will not permit any third party to: (i) remove or obscure proprietary notices; (ii) interfere with or disrupt the Services or attempt to gain unauthorized access to accounts, systems, or data; (iii) reverse engineer, decompile, disassemble, mirror, scrape, or otherwise attempt to derive source code or underlying ideas from the Services except to the limited extent such restriction is prohibited by law; (iv) use the Services in violation of law; or (v) use the Services in a way that creates liability for OpenClinica or its providers.

Customer is responsible for all activity occurring under Customer's accounts except to the extent caused by OpenClinica's breach of these Terms or failure to implement reasonable security controls.

5. Fees, Billing, Taxes, and Suspension

Customer will pay the fees and other charges shown in the applicable Order in accordance with the billing cadence presented during checkout or renewal. Except as expressly stated in these Terms, all fees are non-cancelable and non-refundable once paid.

OpenClinica may charge applicable taxes, and Customer is responsible for sales, use, VAT, GST, and similar transaction taxes associated with the Services, excluding taxes based on OpenClinica's net income, property, payroll, or personnel. If Customer claims a tax exemption, Customer must provide valid exemption documentation in a form acceptable to OpenClinica.

During any renewal term, OpenClinica may change pricing for the Self-Service Plan with at least five (5) business days notice before renewal. If Customer does not agree to the new renewal pricing, Customer may elect not to renew before the renewal date.

Amounts not paid when due may accrue interest at the lesser of one and one-half percent (1.5%) per month or the maximum rate permitted by law. If payment is overdue by sixty (60) days or more, OpenClinica may suspend access to the Services until overdue amounts are paid and may require payment of a reasonable reactivation fee.

To the extent the self-service plan includes usage-based limits, OpenClinica may charge Customer for overages or require Customer to upgrade to a higher plan if Customer exceeds the purchased entitlements.

6. Term, Renewal, and Termination

The initial subscription term begins on the Effective Date or on the service start date identified in the Order and continues for the period stated in the Order. Unless the Order states otherwise, subscriptions automatically renew for successive terms unless either party gives notice of non-renewal at least five(5) days before the end of the then-current term.

Either party may terminate these Terms or the affected Order for material breach if the breach remains uncured for thirty (30) days after written notice describing the breach in reasonable detail. OpenClinica may also suspend or terminate the Services immediately to the extent reasonably necessary to comply with law, protect the Services or other customers, address security or fraud risks, or enforce material use restrictions.

Upon expiration or termination, Customer's and its Authorized Users' rights to access and use the terminated Services cease, except to the extent OpenClinica provides limited post-termination access or export functionality under its standard offboarding workflows, after which OpenClinica may delete Customer Data in accordance with the DPA and its data retention policies

7. Customer Data, Usage Data, and Intellectual Property

As between the parties, Customer retains all right, title, and interest in and to Customer Data, subject to the rights granted in these Terms. Customer represents and warrants that it has all rights, permissions, and authority needed to provide Customer Data to OpenClinica and to authorize OpenClinica to process Customer Data in accordance with these Terms.

Customer grants OpenClinica and its affiliates a non-exclusive, worldwide, royalty-free right to host, copy, transmit, process, display, and otherwise use Customer Data as reasonably necessary to provide, secure, maintain, support, audit, improve, and develop the Services; to create and use de-identified data in accordance with applicable law, the DPA, and any written limitations agreed by the parties; and as otherwise permitted by Customer in writing. OpenClinica will not use such data in a manner that identifies or could reasonably be used to identify Customer or any individual.

OpenClinica and its licensors retain all right, title, and interest in and to the Services, documentation, software, Usage Data, Feedback, and all related intellectual property. Except for the limited rights expressly granted to Customer, no rights are transferred to Customer by implication, estoppel, or otherwise.

OpenClinica may collect and use Usage Data for lawful business purposes, including operating, securing, supporting, improving, benchmarking, and developing the Services, provided that OpenClinica will not disclose Customer Confidential Information except as permitted by these Terms.

To the extent Customer, its personnel, or Authorized Users provide suggestions, enhancement requests, or other feedback regarding the Services ("Feedback"), OpenClinica may freely use and incorporate such Feedback into the Services without restriction or obligation to Customer.

8. Data Protection, Security, and HIPAA/BAA

To the extent OpenClinica processes Personal Data on Customer's behalf in connection with the Services, the DPA applies where applicable and is incorporated into these Terms. The DPA covers, among other things, processing instructions, return and deletion of Personal Data, sub-processor obligations, international data transfer terms, data security, and breach notification.

OpenClinica will maintain commercially reasonable administrative, technical, and physical safeguards designed to protect Customer Data, taking into account the nature of the Services and applicable law.

Where Customer is a HIPAA covered entity or business associate and determines that a Business Associate Agreement is required for Customer's intended use of the Services, Customer must contact legal@openclinica.com. OpenClinica is willing to enter into a Business Associate Agreement with covered entities where appropriate, but no BAA will be effective unless separately executed by authorized representatives of both parties.

Customer acknowledges that some self-service plan features or usage patterns may not be appropriate for regulated or high-risk processing unless Customer has completed its own review of the plan, the DPA, any required BAA, and the Service documentation.

9. Confidentiality

Each party may receive non-public information from the other party that is identified as confidential or that reasonably should be understood to be confidential given the nature of the information and the circumstances of disclosure (“Confidential Information”). Confidential Information does not include information that: (a) becomes public through no fault of the receiving party; (b) was lawfully known to the receiving party without restriction before disclosure; (c) is independently developed without use of the disclosing party’s Confidential Information; or (d) is lawfully received from a third party without a duty of confidentiality.

Each receiving party will use the disclosing party’s Confidential Information only as necessary to exercise rights or perform obligations under these Terms, will protect it using at least a reasonable degree of care, and will disclose it only to personnel, contractors, and advisors who have a need to know and are bound by confidentiality obligations at least as protective as those in these Terms.

If a receiving party is legally required to disclose Confidential Information, it will, to the extent permitted by law, provide prior notice to the disclosing party and disclose only the portion legally required.

In the event of a breach of the confidentiality obligations set forth in these Terms, the parties acknowledge that such breach may cause irreparable harm for which remedies at law would be inadequate, and therefore, the parties agree that such breach will entitle the non-breaching party to seek injunctive relief.

10. Third-Party Providers and Third-Party Materials

The Services may include integrations, embedded functionality, communications tools, hosting services, payment providers, or links to third-party products, websites, or services. Customer may be required to accept additional third-party terms to use certain features.

OpenClinica is not responsible for the content, accuracy, privacy practices, or security standards of third-party materials or third-party providers, except to the extent OpenClinica remains responsible under applicable law or under the DPA for authorized sub-processors processing Personal Data on OpenClinica’s behalf.

11. Warranties and Disclaimer

Each party represents and warrants that: (i) it has the full power and authority to enter into these Terms and to discharge its obligations hereunder; (ii) it will comply with applicable law in performing its obligations hereunder; and (iii) it is not an entity currently excluded, debarred or otherwise ineligible to participate in federal health care programs as defined in 42 U.S.C. § 1320a-7b(f) (the “Federal Health Care Programs”). Each Party agrees to immediately notify the other Party of any change to its eligibility to participate in Federal Health Care Programs, and the other Party has the right to immediately terminate this Agreement in the event of such exclusion, debarment or ineligibility.

OpenClinica further warrants that, during the subscription term, it will provide the Services in a professional and workmanlike manner and that the Services will operate substantially in accordance with the applicable documentation, subject to reasonable downtime, maintenance, updates, and the inherent limitations of software and internet-based services.

EXCEPT AS EXPRESSLY PROVIDED IN THESE TERMS, THE SERVICES, DOCUMENTATION, AND ALL RELATED MATERIALS ARE PROVIDED “AS IS” AND “AS AVAILABLE.” OPENCLINICA DISCLAIMS ALL IMPLIED, STATUTORY, AND OTHER WARRANTIES, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, ERROR-FREE OR UNINTERRUPTED OPERATION, DATA ACCURACY, INTEROPERABILITY, AND WARRANTIES ARISING FROM COURSE OF DEALING OR USAGE OF

TRADE. OPENCLINICA DOES NOT WARRANT THAT EVERY SUPPORT ISSUE OR ERROR WILL BE CORRECTED.

12. Limitation of Liability

TO THE MAXIMUM EXTENT PERMITTED BY LAW, NEITHER PARTY NOR ITS AFFILIATES WILL BE LIABLE FOR ANY INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE, OR CONSEQUENTIAL DAMAGES, OR FOR LOST PROFITS, LOST REVENUE, OR LOSS OF GOODWILL, ARISING OUT OF OR RELATING TO THESE TERMS, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

TO THE MAXIMUM EXTENT PERMITTED BY LAW, EACH PARTY'S TOTAL AGGREGATE LIABILITY ARISING OUT OF OR RELATING TO THESE TERMS WILL NOT EXCEED THE TOTAL FEES PAID AND PAYABLE BY CUSTOMER TO OPENCLINICA UNDER THE APPLICABLE ORDER DURING THE TWELVE (12) MONTHS PRECEDING THE EVENT GIVING RISE TO THE CLAIM.

The exclusions and limits in this Section do not apply to: (a) either party's breach of confidentiality obligations; (b) either party's indemnification obligations; (c) gross negligence, willful misconduct, or fraud; or (d) liabilities that cannot be limited under applicable law. For the avoidance of doubt, the liability limitations in these Terms also apply to claims under the DPA except to the extent applicable law requires otherwise.

13. Indemnification

OpenClinica will defend Customer against third-party claims alleging that Customer's authorized use of the Services infringes a third party's intellectual property rights, and will indemnify Customer against resulting damages, settlement amounts approved by OpenClinica, and reasonable external legal fees, provided that Customer promptly notifies OpenClinica of the claim, gives OpenClinica sole control of the defense and settlement, and provides reasonable cooperation. OpenClinica has no obligation for claims arising from unauthorized modifications, combinations, misuse, or Customer Data.

Customer will defend, indemnify, and hold harmless OpenClinica and its affiliates from third-party claims arising from: (a) Customer Data; (b) Customer's violation of law; (c) Customer's or its Authorized Users' misuse of the Services or breach of these Terms; or (d) Customer's failure to obtain necessary consents, authorizations, or notices.

If both parties contribute to a claim, liability will be allocated in proportion to each party's relative fault to the extent permitted by law.

14. Notices, Changes, and Miscellaneous

OpenClinica may provide operational and legal notices to Customer by email, in-product notification, posting within the account or support portal, or other reasonable electronic means. Customer will keep its account and billing contact information current.

OpenClinica may modify these Terms on a prospective basis by posting updated terms or otherwise notifying Customer. Changes will take effect at the next renewal term unless applicable law requires earlier effectiveness or the change is necessary to comply with law, address security issues, or prevent abuse. Customer's renewal or continued use after the effective date of updated terms constitutes acceptance of the revised terms.

Neither party may assign these Terms without the other party's consent, except in connection with a merger, reorganization, or sale of substantially all assets upon notice to the other party.

These Terms are the complete agreement between the parties regarding the Self-Service Plan and supersede prior or contemporaneous proposals or communications on that subject matter. If any provision is held unenforceable, the remaining provisions will remain in effect. Failure to enforce a provision is not a waiver.

Neither party will be liable for any delay or failure to perform its obligations under these Terms (other than payment obligations) to the extent caused by circumstances beyond that party's reasonable control, including natural disasters, governmental acts or restrictions, labor disputes, failure of third-party infrastructure, or internet disruptions, provided that the affected party promptly notifies the other and uses reasonable efforts to resume performance.

These Terms are governed by the laws of the Commonwealth of Massachusetts, without regard to conflicts of laws principles. The state and federal courts located in Middlesex County, Massachusetts will have exclusive jurisdiction over disputes arising out of or relating to these Terms, except to the extent the DPA requires otherwise.

These Terms will not be governed by the United Nations Convention on Contracts for the International Sale of Goods, or the United Nations Convention on the Limitation Period in the International Sale of Goods, or the Uniform Computer Information Transactions Act, the application of which are expressly excluded.

Questions regarding these Terms, the DPA, or a requested Business Associate Agreement may be directed to legal@openclinica.com.

15. Click-Through Acceptance

By checking the acceptance box, clicking "I Agree," clicking "Purchase," clicking "Start Subscription," submitting the Order, or otherwise accessing or using the Self-Service Plan after being presented with these Terms, the individual accepting these Terms represents and warrants that they have authority to bind Customer and that Customer agrees to be bound by these Terms.

Customer should not click to accept or use the Services if Customer does not agree to these Terms, the applicable Order, and—where applicable—the DPA and any separately executed BAA.

Operational note for implementation

For deployment in production, the checkout flow should require an affirmative unchecked box or equivalent explicit assent, a link to these Terms and the DPA, a retained acceptance log, version control for the posted Terms, and capture of the purchaser name, entity, timestamp, IP/device or equivalent audit metadata, and applicable plan/order details.

Contact for legal requests: legal@openclinica.com