

Randomizer

Terms and Conditions

Revised on 2022-11-08

1. Scope of Services

The Institute for Medical Informatics, Statistics and Documentation at the Medical University of Graz, Auenbruggerplatz 2, A-8036 Graz (the "Provider") provides registered users (the "User") with access to this self-serve Randomization service for multicenter clinical trials (the "Service"), that runs exclusively on the Internet, subject to the terms and conditions set forth in this document (the "Terms and Conditions").

The Provider will offer reasonable levels of continuing technical support to assist Users in the use of the Service. Technical support is provided via e-mail during normal trading hours (local time, i.e. CET/CEST).

Additional Services, particularly for statistical consultation, have to be stipulated separately.

Please note that the meaning of some terms used throughout the Terms and Conditions is explained in the "Definitions" section.

2. Conclusion of Contract with the Provider

The contract enters into force as soon as the Provider receives the completed Trial Registration Form for a trial from the User who is named as the person responsible for the trial (the "Trial Coordinator"). Immediately after receipt of these data (subject to section 12), the Provider will enable the Service for this clinical trial.

3. Period of Validity and Termination

The contract is valid until the duly ending of a clinical trial and its billing and payment.

Randomization for a clinical trial can be terminated by the Trial Coordinator via e-mail at any time. After that, the number of randomizations not yet invoiced at the time of the end or termination will be invoiced. If the number of randomizations included in the basic fee is not exceeded, there is no right to a partial refund, except the money-back-guarantee (according to section 6 below).

Except in default of payment, the Provider is not entitled to terminate the randomization for a clinical trial. The Provider reserves the right to suspend or terminate a User's account in case of misuse of the Service according to section 4 below.

4. Obligations of the User

The User himself/herself is responsible for gaining access to the Service and has to take into consideration that this access may involve third party fees (such as Internet service provider or airtime charges). Additionally, the User must ensure to provide all equipment necessary to access the Service.

In consideration of the use of the Service, the User agrees to provide true, accurate, current and complete information about himself/herself as prompted by the registration form (such information being the "Registration Data"), and maintain and promptly update the Registration Data to keep it true, accurate, current and complete. If the User provides any information that is untrue, inaccurate,

noncurrent or incomplete, or the Provider has reasonable grounds to suspect that such information is untrue, inaccurate, noncurrent or incomplete, the Provider has the right to suspend or terminate the account and refuse any and all current or future use of the Service (or any portion thereof).

The User is responsible for saving his/her clinical trial's data with the help of the export function, which has been made available to the User. It is particularly important to note that with double-blind studies, the generated blinding codes must be retained by the User and be stored, available for emergencies, according to their own security guidelines.

It is the User's duty to keep confidential his/her account and password and to restrict access to his/her computer. Moreover, the User agrees to accept responsibility for all activities that occur under his/her account or password.

5. Remuneration and Terms of Payment

Remuneration is announced at www.randomizer.at. Any increase of remuneration during the entire trial is excluded.

An invoice covering the basic (administration) fee and the included quantity of randomizations will be forwarded to the billing address at after 10 randomizations or 6 months after the first randomization (whichever occurs first), and is due within 30 days of issue. Further invoices will be forwarded quarterly, semi-annually or annually, depending on the Trial Coordinator's choice.

Additional Services will be charged separately.

6. Money-back-Policy

A money-back-guarantee with full refund becomes effective if - within six months after randomization of the first subject - no more than 10 subjects have been randomized into a trial and the Trial Coordinator confirms trial termination.

7. Delay of Payment

Disregard of the terms of payment entitles the Provider to deny the User's further access to the Service. The Provider will inform the Trial Coordinator thereof before.

8. Limitations of Warranties, Liability

The provision of this service is provided on an "as is" and "as available" basis. Any material downloaded or otherwise obtained through the use of the service is done at the User's own discretion and risk and that the User will be solely responsible for any damage to his/her computer system or loss of data that results from the download of any such material.

The Provider expressly disclaims all warranties of any kind, whether expressed or implied, including, but not limited to, the implied warranties of merchantability, fitness for a particular purpose, and non-infringement.

Additionally, the Provider cannot guarantee either the reliability, punctuality, or security, nor the accuracy or reliability of the results of the Service or that the Service is defect free.

If technical errors are brought to the Provider's attention, the Provider will try to correct them. Thus, the User has to state precisely by e-mail why the Service is in error, documenting as clearly as possible why or how the error occurred. The User's help and cooperation is needed to handle requests quickly and efficiently.

The Provider shall not be liable to the User or any third party for any special, incidental, indirect or consequential damage of any kind, or any damage whatsoever, including, without limitation, those resulting from loss of use, data or profits, whether or not the Provider has pointed out to the possibility of such damage, and on any theory of liability, arising out of or in connection with the use of the Service.

The liability of the Provider is limited by the amount outlined in section 5.

The Provider makes no guarantee that through the use of the Service the rights of a third party are not infringed upon or that no other damages are caused. The Provider is not liable for infringement of rights upon third parties or any other damages caused to third parties.

The User agrees to indemnify, hold harmless, and waive all claims against the Provider and its employees, including reasonable attorneys' fees, made by any third party due to or arising out of content he/she makes available through his/her use of the Service, his/her connection to the Service, his/her violation of the Terms and Conditions, or his/her violation of any rights of another. The claim for indemnification is limited to the amount outlined in section 5, unless the underlying claim is based on an intentional or grossly negligent breach of the obligations of the User.

9. Privacy Policy

9.1 Overview

The Provider has developed this Privacy Policy to explain how Personal Data is collected, retained, processed, shared and transferred when Users visit the Provider's websites or use its Services. This Privacy Policy applies to the User's personal information when visiting the Provider's websites or using Services and does not apply to websites or services that the Provider does not own or control. The Privacy Policy is designed solely to provide Users with information about the Provider's privacy practices and to demonstrate what privacy options are available to them when they use the Provider's websites and Services. For further questions on data protection aspects, please refer to the section "Contact for Data Protection Issues".

9.2 What Personal Data is Collected?

The Provider collects Personal Data when users visit the Provider's websites or use the Provider's Services. This includes the following information:

- **Registration and use information:** When Users register to use the Provider's Services by creating a user account, the Provider collects the Personal Data necessary to provide the requested Services. Depending on the Services selected, it may be necessary to provide name, address, phone number, email address and other identification information in order to set up an account. Users may be asked to provide additional personal information when using the Provider's services.
- **Action information:** When Users access the Provider's websites or use the Provider's services, the Provider collects information about the actions performed and other information related to the actions, such as Device Information and Technical Usage Data.
- **Other data collected:** The Provider may collect additional information from or about Users when they communicate with the Provider, contact the Provider's customer support or participate in a survey.

9.3 Why is Personal Data Retained?

The Provider shall keep Personal Data in an identifiable format for the least amount of time necessary to fulfill the Provider's legal or regulatory obligations and for the Provider's business purposes. If an account has been deactivated, the Provider can take measures to continue using data in anonymous form.

9.4 How is Personal Data Processed?

The Provider processes Personal Data of Users for the following reasons, which are permitted under the data protection laws of the European Union:

- **To operate the websites and provide the Services, including to:**
 - authenticate access to an account,
 - manage the association of user accounts to different trials,
 - communicate with Users regarding their account and the Provider's services, for example, to respond to questions Users have directed to the Provider's support team.

- To manage the Provider's business needs, such as billing, monitoring, analyzing and improving the performance and functionality of websites and Services. For example, the Provider analyzes User behavior and the use of its Services.
- For the Provider's legitimate interests, including to enforce the Terms and Conditions of the Provider's websites and Services.

9.5 When is Personal Data Shared?

For business reasons, the Provider may share Personal Data with third parties if such disclosure is legally permissible or necessary. This applies in particular in the following cases:

- if the Provider is obliged to comply with the law, legal process or regulations, for example in the context of criminal prosecution, a court order or other legal processes, if the Medical University of Graz is affected;
- if the Provider believes that the disclosure of Personal Data is necessary and appropriate to prevent physical damage or financial loss or to support the investigation of a possible or actual illegal activity;
- to investigate violations of the terms or other legal provisions applicable to Provider's services or to enforce these legal instruments;
- to protect the Provider's assets, services and legal rights;
- to the Provider's banking partners;
- to credit reporting and collection agencies, and
- to support the functions of the Provider in the areas of audit, compliance and corporate management.

In addition, the Provider may share aggregated statistical information with third parties to understand how, when and why Users access the websites and use the Provider's Services. Users cannot be personally identified with this data. The data does not contain any information on the use of the websites or Services by identifiable individuals. The Provider does not share Personal Data with third parties for their marketing activities without the consent of the respective persons.

9.6 How are Cookies and Tracking Technologies Used?

When Users visit the Provider's websites or use its Services, the Provider may use cookies and other tracking technologies (from now on collectively referred to as "cookies") to identify Users as authorized customers. Some aspects and functions of the Provider's websites and Services are only available using cookies. If Users deactivate or reject cookies, the use of the websites and services may be restricted or may no longer be possible.

Do Not Track (DNT) is an optional browser setting that allows users to express their preferences regarding tracking by advertisers and other third parties. The Provider does not respond to DNT signals.

9.7 What Privacy Choices are Available?

Users have certain choices when it comes to the privacy practices and communications described in this Privacy Policy. Many choices may be explained at the time when using the website, registering for, or using a Service. Users may be provided with instructions as they navigate through the website or Service.

- **Choices relating to registration and account information:** When Users have an account they can usually review and edit personal information by logging in and correcting the information themselves or by contacting the Provider. If Users do not have an account or if they have questions about account information or other Personal Data, they can contact the Provider.
- **Choices relating to the collection of Personal Data:** Users may refuse to provide Personal Data to the Provider if requested by the Services. In this case, however, certain or all Services may be unavailable to Users.
- **Choices relating to communication:** The Provider sends messages to Users that are required or necessary for all customers of the Services, notifications that contain important information, and other messages that Users request from the Provider. Some of these messages cannot be unsubscribed by Users.

- **Choices relating to cookies:** Users have several options to manage their cookie settings. Depending on the browser or Internet device, Users can delete, deactivate or block certain cookies or tracking technologies. Users can use these options; however, this may prevent them from using basic functions of the Provider's websites or Services. Further information can be found at www.aboutcookies.org.

9.8 What Rights do Users Have?

Subject to limitations set out in the European GDPR, Users have certain rights in respect of their Personal Data. In particular, they have a right of access, rectification, restriction, opposition, erasure, and data portability. Users should contact the Provider if they wish to exercise these rights; credible proof of the User's identity must be provided.

If a User has an account with one of the Provider's services, they can usually check and edit personal information in that account by logging in and directly updating the information.

9.9 How Does the Provider Protect Personal Data?

The Provider maintains organizational, physical, technical and administrative security measures designed to provide reasonable protection for Personal Data against loss, misuse, unauthorized access, disclosure, and alteration. The security measures include firewalls, data encryption, physical access restrictions to data centers, and authorization controls for access to data. While the Provider is dedicated to securing its systems and services, Users are responsible for securing and maintaining the privacy of their password(s) and account registration information and verifying that the Personal Data the Provider maintains about them is accurate and current.

9.10 Contact Regarding Data Protection Issues

Users may contact the Provider at any time if they have questions or concerns regarding this Privacy Policy, additional notices or the handling of Personal Data. The Provider's data protection officer can be reached at datenschutz@medunigraz.at.

If Users are not satisfied with the way in which the Provider addresses their concerns, they have the right to lodge a complaint with the supervisory authority for data protection in their country.

10. Modification and Severability

The Provider reserves the right to change the site, policies, and these Terms and Conditions at any time at its sole discretion without notice to the User. The Provider will notify Users of any significant changes to this Terms and Conditions at least 14 days prior to the effective date of the changes on the Provider's website and Trial Coordinators by e-mail or otherwise. The User can object to the change within 14 calendar days, otherwise the changed Terms and Conditions apply to the contract between Provider and User. In the event of an objection by the User, the Provider is entitled to premature termination of the contract by written notice subject to a period of notice of 14 calendar days; billing shall be in accordance with section 3 of the Terms and Conditions.

The most current version of the Terms and Conditions is made available on the website www.randomizer.at.

If any provision or provisions of these Terms and Conditions shall be held to be invalid, illegal, unenforceable or in conflict with the law of any jurisdiction, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

11. Final Provisions

No modification or claimed waiver of any provision of this agreement shall be valid except by written amendment signed by the Trial Coordinator and the authorized representatives of the Provider.

If the User becomes aware of any violations of these Terms and Conditions, the User is requested to notify the Provider as soon as possible. Although the Provider cannot guarantee that action will be taken as a result of the notification, any feedback is welcome.

12. Austrian Consumer Protection Act of 1979

The Services may not be acquired by consumers as defined in the Austrian Consumer Protection Act of 1979 in its current form. The Provider explicitly retains the right to inform any consumer wishing to fill out or having filled out the registration form that no contract is or has been concluded. However, this is only an information, as no offer is given by the Provider.

13. Definitions

- **Device Information** means data that can be automatically collected from any device used to access the Site or Services. Such information may include, but is not limited to, the device type; the device's network connections; the device's name; the device's IP address; information about the web browser and internet connection used to access the Site or Services.
- **Personal Data** means information that can be associated with an identified or directly or indirectly identifiable natural person. "Personal Data" can include, but is not limited to, name, postal address (including billing and shipping addresses), telephone number, email address, payment card number, other financial account information, account number, date of birth, and government-issued credentials (e.g., driver's license number, national ID, passport number).
- **Provider** means the Institute for Medical Informatics, Statistics and Documentation at the Medical University of Graz, Auenbruggerplatz 2, A-8036 Graz.
- **Registration Data** means information entered in the registration form while creating an account.
- **Services** means any products, services, content, features, technologies, or functions, and all related websites, applications and services offered to you by the Provider with an account.
- **Technical Usage Data** means information collected from the User's phone, computer or other device that is used to access the website or Service. Technical Usage Data tells the Provider how Users use the websites and Services, such as what they have searched for and viewed on the websites and the way they use the Services, including the IP address, statistics regarding how pages are loaded or viewed, the websites visited before coming to the websites and other usage and browsing information collected through cookies.
- **Trial Coordinator** means the User named in the Trial Registration Form as the responsible person for the trial.
- **User** means an individual who uses the Services or accesses the websites and has established a relationship with the Provider (for example, by opening an account and agreeing to the Terms & Conditions) or otherwise uses the Services.