

**General Terms & Conditions for Use Of Reed Tech® Navigator for Medical Devices**  
**Effective January 24, 2020**

These terms and conditions listed below govern your use of the Reed Technology Information Services, Inc. ("Reed Tech", "LN" or "LexisNexis") Navigator for Medical Devices (the "Service") provided to you by Reed Tech. The terms "you" and "your" in uppercase or lowercase shall mean the entity (e.g., company, corporation, partnership, sole proprietor, etc.) or government agency entering into a license agreement with Reed Tech for the Service. The "License Agreement" or "Agreement" shall consist of these General Terms and the Order. This Agreement sets forth the terms and conditions under which Reed Tech provides you access to the Service. By using the Service, you agree to be bound by this Agreement.

**1. DEFINITIONS**

1.1 **"Affiliate"** of a party means a corporation, partnership, or other legal entity that controls, is controlled by, or is under common control with that party, either directly or through another affiliate, but only while that control relationship exists; "control" of an entity means the power to direct the management and policies of that entity through a controlling vote on the board of directors or similar governing body of that entity or the ownership of interests entitled to more than 50% of the votes of that entity.

1.2 **"Authorized User"** means an individual to whom you have assigned a Reed Tech Username and who otherwise qualifies to use the Service under the terms of this Agreement.

1.3 **"Customer Data"** means information, data, files, or documents containing information that you enter into the Service.

1.4 **"Force Majeure"** means a cause which is beyond a party's reasonable control, including but not limited to fire, riot, civil disturbance, strike, embargo, explosion, earthquake, volcanic action, flood, act of military authority, act of terrorism, act of God, and act or omission of a carrier or supplier.

1.5 **"Misuse"** means using the Services in a manner other than as permitted under this Agreement. Examples of Misuse include, but are not limited to, gaining or allowing unauthorized access to and use of the Services prohibited hereunder, sharing access to any User ID with any person, altering any component of the Service, interfering or interrupting networks connected to the Service, uploading or introducing to Service viruses, corrupted files or other such malicious software that may damage the operation of the Service.

1.7 **"Order"** means an Order that refers to this Agreement, is signed by representatives of Reed Tech and your organization and describes the particular Service that Reed Tech will provide and the pricing associated with the Service.

1.8 **"Service Materials"** means content, information, data, files, or documents provided by the Service that was not entered by you.

1.9 **"Username"** means a unique identifier and password (or other authentication or security

measures) that enable access to and use of the Service.

## 2. LICENSE

The Service is furnished as a software-as-a-service. Subject to these terms, Reed Tech grants to you a limited, non-transferable, non-assignable, non-exclusive personal license for Authorized Users to use the Service for you as set forth in an applicable Order. Only your employees, temporary employees, students, partners/members, and contractors dedicated to performing work exclusively for you (to the extent those categories of persons are appropriate to your situation) are eligible to access and use the Service ("Eligible Persons"). Without limitation, external professional service providers such as attorneys, accountants, consultants, outsourcers and public relations firms are specifically excluded from being Eligible Persons. The term "Authorized User" means an Eligible Person whom you have identified to Reed Tech for purposes of issuing a Reed Tech Username. You agree that each Reed Tech Username may only be used by the Authorized User to whom Reed Tech assigns it and that the Reed Tech Username may not be shared with or used by any other person, including other Authorized Users. You will manage your roster of Authorized Users and will promptly notify Reed Tech to deactivate an Authorized User's Reed Tech Username if the Authorized User is no longer an Eligible Person or you otherwise wish to terminate the Authorized User's access to the Online Services. You are responsible for all use of the Service accessed with Reed Tech Usernames issued to your Authorized Users, including associated charges, whether by Authorized Users or others. You will use reasonable commercial efforts to prevent unauthorized use of Reed Tech Usernames assigned to your Authorized Users and will promptly notify Reed Tech, in writing, if you suspect that a Reed Tech Username is lost, stolen, compromised, or misused.

You may not, nor may you allow any third party to, (a) modify, adapt, translate or create derivative works of the Service; (b) decompile, disassemble, reverse engineer, or otherwise attempt to discern the source code of the Service; (c) download, scrape, reconstruct, or otherwise reproduce the Service Materials in their entirety or substantially in their entirety, (d) search the Service via mechanical, programmatic, robotic, scripted or any other automated means, unless otherwise agreed to by Reed Tech in writing; (d) sublicense, copy, transmit or distribute the Software; (e) use the Service on a time-sharing or service bureau basis; or (f) permit use by a person other than Authorized Users.

Reed Tech owns the Service and all developments, innovations and intellectual property associated with the Service.

We may update the software and technology used to provide Service, as we in our sole discretion, may deem necessary or desirable, from time to time. All updates and other new versions of the technology used to provide the Service are covered by these terms as part of the Service.

## 3. REPRESENTATIONS AND WARRANTIES

3.1 You represent and warrant to Reed Tech as follows: (a) you will employ the Service solely for Your own use in the ordinary course and conduct of Your business; (b) you have the authority to execute and deliver this Agreement and to perform the obligations under this Agreement; (c) your execution, delivery and performance of this Agreement will not violate any law or regulation or any other agreement to which you are a party; (d) you will not use any information from the Service for any purpose not expressly permitted in this Agreement or otherwise authorized in writing by Reed Tech; and (e) all information, inclusive of that you provide to Reed Tech will be true and complete and may be relied on and used by Reed Tech for the provision of the Service provided in connection with this Agreement.

3.2 Reed Tech represents and warrants to you: (a) the Service will perform in a manner consistent with its documentation and specifications; and (b) the execution, delivery and performance of this Agreement by Reed Tech will not violate any other agreement to which Reed Tech is a party; and With respect to a breach of the warranty identified in subparagraph (a) above, Reed Tech will, after written notice, use commercially reasonable efforts to correct any identified material errors in the performance of the Service. That corrective action will constitute Reed Tech's sole liability and your sole remedy with respect to any identified performance error.

3.3 You acknowledge the risk that information transmitted electronically between you and Reed Tech through the Service website or other means may be intercepted by third parties. You agree to accept that risk and will not hold Reed Tech liable for any loss, damage or injury resulting from the interception of information.

3.4 You warrant that you shall comply with all applicable laws, rules, regulations, directives and guidelines regarding the collection, use and disclosure of personal data, including without limitation the General Data Protection Regulation 2016/679, The Data Protection Act 2018 and any amendments or successors to those laws ("Applicable Privacy Laws") when processing personal data in relation to the Service. You shall provide all reasonably necessary assistance to Reed Tech to enable Reed Tech to comply with Applicable Privacy Laws.

#### **CONFIDENTIAL INFORMATION**

4.1 "**Confidential Information**" means (a) all components of the Service, including without limitation, all non-public information and all Usernames and passwords issued; (b) each parties' intellectual property; (c) all other proprietary documentation and information relating to or exchanged through the Service from either party that is marked as confidential, proprietary or the like; and (d) the terms of this Agreement.

4.2 Neither Reed Tech nor you will disclose to any entity (except to its employees, representatives, agents or contractors having a need to know the Confidential Information and who are subject to confidentiality obligations no less restrictive than those herein) or use, except as permitted by this Agreement, any Confidential Information it receives from the other pursuant to this Agreement. Reed Tech and you will each exercise reasonable efforts, but in no event less than the same degree of diligence as it exercises in protecting its own trade secrets, to safeguard the Confidential Information and to prevent its unauthorized use or disclosure.

4.3 Confidential Information does not include information already known to the receiving party before the date of disclosure, information available to the public, information received from a third party who is not bound by an obligation to keep it confidential or information independently developed or acquired by or for the receiving party.

4.4 If either party is required by law to make any disclosure of Confidential Information that is prohibited or otherwise constrained by this Agreement, then such party will provide the other party with prompt written notice of such requirement (to the extent permitted by law) prior to such disclosure so that the other party may seek a protective order or other appropriate relief. Subject to the foregoing sentence, the party required to make any such disclosure may furnish that portion (and only that portion) of the Confidential Information that it is legally compelled or otherwise legally required to disclose.

## **5. EXCLUSION FROM USE OF THE SERVICE**

If any action, proceeding, claim or dispute arises between you and Reed Tech over your Misuse of the Service, You acknowledge that your Misuse of the Service constitutes a breach of this Agreement and that under such circumstances Reed Tech will have the right to either suspend your right to use Service pending any resolution of the dispute or terminate your access to the Service.

## **6. ADMINISTRATIVE, OWNERSHIP, AND LIMITATION ON USE**

6.1 You agree to provide and update all information that is reasonably necessary in order for Reed Tech to provide the Service to you.

6.2 Reed Tech is not responsible for the accuracy, completeness or integrity of any data that you provide or enter into the Service via any means. Reed Tech does not warrant the accuracy of data in reports generated using any data you provide including Customer Data and expressly disclaims responsibility for the results obtained through reports and/or outputs designed and generated by you using the Service. You are solely responsible for all data validation in any reports and outputs designed and generated by you.

6.3 You acknowledge that the Service is not a substitute for your independent medical and professional judgment regarding the risks posed by medical devices or their manufacturers. You remain solely and exclusively responsible and liable at all times for compliance with all applicable laws and regulatory requirements related to identification, trending, analysis, or reporting of medical device safety and quality risks, including but not limited to all FDA requirements.

6.4 Except for your Confidential Information that you provide to Reed Tech, you acknowledge that Reed Tech or its licensors own all intellectual property and other rights to the Service website and registries, and to all software, databases and tangible and intangible Service Materials embodied in them or relating to them, including without limitation, all raw, gross or compiled statistical information and other data obtained, assembled or developed by Reed Tech in the course of providing its Service, all software modifications, all derivative works, and all copyright, patent, trademark, trade secret and other intellectual property or other rights to them, without any obligation to you or any third party (collectively, the "Reed Tech Intellectual Property"). Nothing contained in this Agreement will be construed to convey any title or ownership right in any of the Reed Tech Intellectual Property to you, or any right to use any of the Reed Tech Intellectual Property other than as expressly contemplated by this Agreement and these Terms. You may not remove any of Reed Tech's copyrights, patents, trademarks, or other proprietary notices contained on the Service website or in any other documentation or Service Materials available to you through the Service. Reed Tech may modify, delete, amend or change its registries, applications, products and the Service at its sole discretion.

## **7. FEES**

7.1 You acknowledge and agree that, in order to use and continue using the Service, You are required to pay the required fees set forth in the applicable Order in a timely manner. Fees do not include any federal, state or local sales, use, or similar taxes. If any such taxes are applicable, you shall be solely responsible for payment of such taxes.

7.2 All payments due to Reed Tech hereunder are to be paid in U.S. dollars and are due within thirty (30) days of the date of the applicable invoice. Payments provided for herein shall, when overdue, be subject to a late payment charge calculated at a rate of one and one-half percent (1.5%) per month until paid; provided, however, that if the amount of such late payment charge exceeds the

maximum permitted by law for such charge, such charge shall be reduced to such maximum amount. You shall be liable for all costs of collection incurred by Reed Tech including, without limitation, collection agency fees, reasonable attorneys' fees and court costs if you fail to comply with the payment obligations set forth herein.

7.3 At Reed Tech's option, the entire amount due for the Service and under any other agreement that you may have with Reed Tech shall become due and payable upon Your breach of any term, provision or condition herein or of any other agreement that You may have with Reed Tech.

## **8. DISCLAIMERS; LIMITATION OF LIABILITY; INDEMNIFICATION**

8.1 Reed Tech assumes no responsibility or liability regarding any information provided by you or any action taken by You in connection with the Service. Without limiting the foregoing, EXCEPT AS SPECIFICALLY PROVIDED IN THIS AGREEMENT, REED TECH DOES NOT WARRANT AND EXPRESSLY DISCLAIMS ANY LIABILITY FOR THE ACCURACY, COMPLETENESS, CURRENTNESS, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF THE INFORMATION OR SERVICE MADE AVAILABLE THROUGH THE SERVICE. EXCEPT AS SPECIFICALLY PROVIDED IN SECTION 3 ABOVE, REED TECH PROVIDES NO WARRANTIES, EXPRESS OR IMPLIED, ORAL OR WRITTEN, WITH RESPECT TO THE SERVICE. The Service's software or other methodology by which the Service are rendered is provided "AS IS."

8.2 YOU AGREE THAT THE LIABILITY OF REED TECH, ITS AFFILIATES, AND AGENTS, ARISING OUT OF ANY CLAIM THAT IS IN ANY WAY CONNECTED WITH THE SERVICE, WILL NOT EXCEED THE TOTAL AMOUNT YOU HAVE PAID FOR THE SERVICE PURSUANT TO THIS AGREEMENT WITHIN THE TWELVE MONTH PERIOD BEFORE THE DATE THE CLAIM AROSE. YOU FURTHER AGREE THAT REED TECH IS NOT AND WILL NOT BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND WHATSOEVER (INCLUDING WITHOUT LIMITATION, ATTORNEYS' FEES) RELATING TO THIS AGREEMENT OR THESE TERMS. THESE DISCLAIMERS APPLY, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE, WHETHER THOSE DAMAGES ARE FORESEEABLE AND WHETHER REED TECH HAS BEEN ADVISED OF THE POSSIBILITY OF THOSE DAMAGES; PROVIDED THAT THESE DISCLAIMERS WILL NOT BE APPLICABLE TO THE EXTENT DAMAGES ARISE FROM REED TECH'S GROSS NEGLIGENCE OR FRAUDULENT OR INTENTIONAL MISCONDUCT AND WILL NOT BE APPLICABLE TO REED TECH'S INTELLECTUAL PROPERTY INDEMNIFICATION OBLIGATION SET FORTH IN SECTION 8.4 BELOW.

8.3 You agree to defend and indemnify Reed Tech and its Affiliates, directors, officers, agents, employees and consultants from any claims, actions, proceedings, costs, liabilities, judgments, obligations, penalties, losses, costs, expenses or other damages (including reasonable attorneys' fees and expenses) sustained by Reed Tech and its Affiliates or consultants by reason of any third party claims related to your use of the Service, including but not limited to any claims involving your analysis and interpretation of the Service Materials, misuse of the Service, infringement of any Reed Tech Intellectual Property, or your compliance with applicable laws and regulatory requirements in relation to identification, trending, analysis, or reporting of medical device safety and quality risks or any other applicable laws and regulatory requirements. Reed Tech will provide notice to you of any indemnifiable event or loss. You will undertake, at your own cost, the defense with counsel reasonably acceptable to Reed Tech. Reed Tech reserves the right to participate in the defense of the claim, suit or proceeding, at its expense, with counsel of its choosing. Reed Tech may participate in the defense of the claim, suit or proceeding, at its expense, with counsel of its choosing.

8.4 Reed Tech agrees to defend and indemnify you against any claims, actions, proceedings, liabilities, judgments, obligations, penalties, losses, costs, expenses or other damages (including reasonable attorneys' fees and expenses) sustained by you by reason of a third party claim that the Service's software (except for third party content or software) utilized by Reed Tech to provide the Service for you infringes a U.S. copyright. You agree to promptly provide notice to Reed Tech of any indemnifiable event or loss and will cooperate with Reed Tech in defending the event or loss. Reed Tech will undertake the defense of the claim, suit or proceeding. You may participate in the defense of the claim, suit or proceeding, at your expense, with counsel of Your choosing.

## **9. RIGHT TO USE AND RESTRICTIONS ON USE**

9.1 You acquire only the limited, non-assignable, non-transferable, terminable right to use the Service and Service Materials and do not acquire any right of ownership in them. You may not distribute, modify, reverse engineer or reproduce the Service or any component of the Service. You may not download, scrape, reconstruct, or otherwise reproduce the Service Materials in their entirety or substantially in their entirety. Use of the Service via mechanical, programmatic, robotic, scripted or any other automated means is strictly prohibited. Unless otherwise agreed to by Reed Tech in writing, use of the Service is permitted only via manually conducted, discrete, individual search and retrieval activities. All rights in and title to the Service and Service Materials, including all intellectual property rights, are owned by Reed Tech or its licensors.

9.2 You may use the Service solely for your own business purposes and operations. This right to use the Service will end immediately upon termination of this Agreement. You agree to implement policies and procedures to prevent unauthorized access to and use of Usernames and the Service and will immediately notify Reed Tech in writing if you suspect that a Username to the Service is lost, stolen, compromised or Misused. You agree to fully reimburse Reed Tech for any labor and expenses incurred due to your failure to prevent unauthorized use of the Usernames and the Service, notwithstanding any conflicting provisions or limitations in this Agreement.

## **10. ROUTINE AND EMERGENCY MAINTENANCE; SUPPORT**

10.1 The Service is provided to you with the expectation that it will be available for your use 99.8% of each calendar month while this Agreement is in effect and as further specified in this Section 10.1. In the event the Service is not available for Your use 99.8% of each calendar month while this Agreement is in effect and you meet all of your obligations under this Agreement, You may be eligible for credits for periods when the Service is unavailable due to an Outage, which credits will be determined at Reed Tech's sole discretion and as further specified in this Section 10.1. You understand and agree that Reed Tech will periodically perform routine and emergency maintenance on the Service as needed and that no credits will be made to you for any period of time the Service is unavailable for routine or emergency maintenance. An "Outage" is defined as an inability to utilize the Solution due to a failure in the network, hardware or software; provided, however, an Outage does not include any period of unavailability of the Service attributed to acts or omissions of you or your Authorized Users, or failure of your network or equipment, including any mobile device and associated services, Force Majeure events, fiber cuts caused by third-parties, failure of elements of the Internet or third party products or services outside of Reed Tech's control, or unavailability occurring during Reed Tech's routine or emergency maintenance of the Solution. Reed Tech will make efforts to perform routine or scheduled maintenance during its non-peak hours and with advance notice to you.

10.2 Reed Tech will make a member of its support staff available via telephone ("Telephone Support") to Your System Administrator to assist you in the standard business use of the Solution.

Your System Administrator will provide the first line technical support of the Services to You and Your Authorized Users. Telephone Support shall be available 8:00 am – 8:00 pm Eastern Time Monday through Friday, excluding holidays recognized by Reed Tech, at **215-682-8282**.

## **TERM AND TERMINATION**

11.1 The "Term" of this Agreement commences on the effective date set forth in the applicable Order and will continue until terminated as set forth below or in the applicable Order. If You fail to pay the fees, set forth in the applicable Order, when due, Reed Tech may suspend Your access to the Service until such time as all past due fees have been paid.

11.2 This Agreement may be terminated by either party on or before the expiration of the Term via written notice if the other party: (i) breaches any confidentiality or non-disclosure obligation, (ii) breaches any other material term or condition of this Agreement and fails to remedy any breach within thirty (30) days after receiving notice, (iii) becomes the subject of any voluntary or involuntary proceeding under the U.S. Bankruptcy Code or any state insolvency proceeding, or (iv) ceases to be actively engaged in business.

11.3 On the expiration or termination of this Agreement: (i) you will pay amounts owed to Reed Tech in accordance, (ii) all Usernames and Passwords issued to you to access the Service will be deactivated, (iii) you will deliver to Reed Tech all manuals, software, documents and other Reed Tech Intellectual Property and Confidential Information in your possession, and (iv) if appropriate, the parties will assess the appropriate means of returning and/or destroying Your content.

## **12. NOTICES**

12.1 Notices by email will be deemed duly made, except for notices of termination, insolvency or legal action, which must be made in writing and (i) sent by overnight courier; or (ii) mailed by certified mail.

To REED TECH:

Reed Tech  
Attention Chief Legal Officer  
9443 Springboro Pike  
Miamisburg, OH 45342

To YOU: Your address in the Order

12.2 Reed Tech will provide routine product notices (e.g., information regarding features, content, or maintenance) to you via email only, addressed to you or the appropriate Authorized User(s); email notice is deemed sufficient for such purposes.

## **13. MISCELLANEOUS**

13.1 Assignment. No party may assign or otherwise transfer this Agreement without the prior written consent of the other party except that Reed Tech may assign this Agreement in its entirety to any purchaser of all or substantially all of its business or assets pertaining to the line of business to which this Agreement relates or to any subsidiary or other Affiliate of the party without approval. As a

condition to any assignment, the assignee must agree to assume and be bound by this Agreement in its entirety.

**13.2 Privacy.** When using the Service, you may be asked to provide certain information to us. Your use of the Services must comply with all applicable laws, rules or regulations. You will comply with all applicable laws and regulations in supplying any personal data to Reed Tech, including providing any required notices and obtaining any required consents, permissions and authorizations for Reed Tech processing such personal data. Our use of any information you provide or otherwise collected by us through the Service are governed by our Privacy Policy, the current version of which is available at [lexisnexis.com/en-us/terms/privacy-policy.page](https://www.lexisnexis.com/en-us/terms/privacy-policy.page). If and to the extent that Reed Tech is processing personal data on Your behalf, the terms of the LexisNexis data processing addendum at <https://www.lexisnexis.com/en-us/terms/processor-terms.page> will apply.

**13.4** You are neither identified on, nor shall you provide access to Service to any individuals identified on, (1) OFAC's list of Specially Designated Nationals ("SDN List"), (2) the UK's HM Treasury's Consolidated List of Sanctions Targets, (3) the EU's Consolidated List of Persons, Groups, and Entities Subject to EU Financial Sanctions, (4) any other applicable sanctions lists, or (5) any person fifty percent (50%) or more owned, directly or indirectly, individually or in the aggregate by a person(s) identified in (1) through (4).

**13.5 Force Majeure.** Neither party will be liable for any failure or delay in performing any obligation under this Agreement that is due to a Force Majeure. If a Force Majeure occurs, the affected party will notify the other party and make commercially reasonable efforts to mitigate the adverse effects of the Force Majeure on the performance of this Agreement. This Section does not excuse Your obligation to pay for Service actually received.

**13.6 Waiver.** No waiver of any breach, privilege or provision of this Agreement will be construed as a waiver of any rights or remedies arising from any other breach, privilege or provision.

**13.7 Survival.** The obligations of Sections 1–8, 11.3, and 12 of this Agreement shall survive any termination of this Agreement and any accrued but unpaid financial obligations, and any other terms related to such financial obligations that by their nature should or typically would survive expiration or termination will survive the expiration or termination for any reason of this Agreement.

**13.8 Amendments and Waivers.** This Agreement may not be modified or amended except by a written instrument signed by an authorized representative of each of the parties, except that Reed Tech may change these terms from time to time, immediately, if such changes are required because of Reed Tech licensor, governmental, or regulatory requirements ("Compliance Mandates"). Compliance Mandates will be made immediately upon notice to You by way of updating these terms electronically. If such Compliance Mandates are made, they will be applied prospectively and will not be specifically directed against You but will apply to all similarly situated customers. Any failure of a party to comply with any obligation contained herein may be waived by the party entitled to the benefit thereof only by a written instrument signed by an authorized representative of the party granting such waiver. No failure on the part of any party to exercise, and no delay in exercising, any right or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any right or remedy hereunder preclude any future exercise thereof or the exercise of any other right or remedy.

**13.9 Choice of Law.** The Commonwealth of Pennsylvania law governs the interpretation and enforcement of this Agreement, regardless of the law that might otherwise apply under applicable principles of conflicts of law.