

DATA COLLECTION AGREEMENT

MASTER TERMS

RECITALS

WHEREAS, CDR has developed the U.S. Wound Registry (“USWR”), to collect and report on standardized national clinical wound care data in connection with different wound care related procedures and conditions; and

WHEREAS, the USWR provides a mechanism that permits medical practices to make comparisons between performance in specific areas covered by the USWR and like national or regional summary data on performance in order to advance medical practices’ quality improvement initiatives; and

WHEREAS, the USWR currently comprises five (5) registries known respectively as the U.S. Wound Registry™, the National Podiatric Medicine Registry™, the Do The Right Thing Registry™, the Hyperbaric Registry™, and the Cytomedix Coverage with Evidence Development (“CED”) Registry, and may in the future include other registries in which medical practices may elect to participate; and

WHEREAS, Practice desires to participate in the USWR to improve the quality of its patient care; and

WHEREAS, CDR is willing to permit Practice to participate in the Registry in consideration for the grant of rights and other consideration set forth in this Agreement.

NOW, THEREFORE, in consideration of the mutual promises and Agreements set forth, including the Recitals, which are incorporated into this Agreement as substantive terms, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by CDR and Practice:

IT IS AGREED:

1. Business Associate. The Parties agree that because CDR is providing benchmarking and data aggregation services to Practice, the CDR qualifies as a “Business Associate” of Practice under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).
2. Participation in the Registry. By signing this Agreement, Practice is enrolled in the Registry. Practice may choose to submit clinical data to the Registry upon assignment of data collection resources. Practice may allow as many of its physical offices within the Practice to participate in the Registry as it desires.
3. Practice Responsibilities.
 - a. Submission of Clinical Data. After implementing the data collection initiative, Practice will furnish clinical data. Such data will be evaluated for data quality upon submission and the CDR will provide guidance to ensure high quality data standards.
 - b. Selection of Data Collection Method. Upon implementation of the data collection initiative, Practice will select a CDR approved data collection method. Current data collection methods include: collection through a CDR approved EMR and collection through a CDR approved System Integration Solution.
 - c. Point of Contact. Practice will select a staff member to be the primary contact for the Registry.
 - d. Data Evaluation. Practice understands that its submitted data may be reviewed for accuracy and completeness by the CDR.

e. Release of Physician Specific Data. Physicians will be asked to sign a data release consent form for any reporting program in which Practice participates to authorize CDR to submit physician level data to any third party. The data release consent form will identify the applicable reporting program. The execution of the data release consent form is voluntary and not a requirement of participation in the Registry.

f. Data Confidentiality. Practice shall maintain appropriate procedures to protect data confidentiality in compliance with applicable law. Practice will be solely responsible for any and all of its acts or omissions that may affect the privacy or security of data it furnishes hereunder. Practice shall maintain appropriate liability insurance or a program of self-insurance for its acts and omissions under this paragraph.

g. Practice of Medicine. The reports and tools provided by the CDR are for quality assurance and improvement only and are not intended to direct clinical decision making as to the care of individual patients of Practice. Practice represents and warrants that Practice and the physicians affiliated with Practice are solely responsible for clinical decision-making and the exercise of sound medical judgment in the care and treatment of patients of the Practice.

4. CDR Responsibility.

a. Acceptance of Data. CDR agrees to accept Practice's clinical data that are submitted on a timely basis. CDR reserves the right to reject data submission in its entirety, or to limit the use of such Practice data, including new data as set forth in Section 3.d. above if data does not conform to the requirements of the Registry. Further, as outlined above, data may only be accepted if submitted using a data collection method approved by CDR.

b. Reports. CDR shall generate quality assurance and improvement oriented outcome reports periodically based on Practice's submitted data and distribute reports to Practice. Such reports shall include aggregated demographic, general information and patient outcomes in a form made available by CDR to Practices and as updated by CDR.

c. Use of CDR Data Set. CDR reserves the right to produce, disseminate, and revise the data elements, definitions and formats when deemed necessary.

d. Training. CDR shall make available to Practice a training mechanism to guide Practice through data collection activities.

e. Data Accuracy. CDR shall analyze the Practice's submitted data records, by means of electronic data checks, consistency checks and range checks, to assess data accuracy and completeness.

5. Data and Copyright Ownership.

a. Individual Patient Data. The data for individual patients submitted by Practice shall be the exclusive property of Practice, subject to the rights, if any, of the Practice's patients in Individually Identifiable Health Information, and subject to the rights granted to CDR in this Agreement and the Business Associate Agreement. Practice hereby agrees that the return of that information is infeasible, as it will have been integrated into the Registry and the related, proprietary databases of CDR. Practice hereby grants to CDR a perpetual, enterprise-wide, royalty-free license, that is worldwide and in all forms and all media (including derivative works), to use the data of or relating to individual patients, including Individually Identifiable Health Information submitted by Practice in such manner that is consistent with this Agreement. To the extent CDR de-identifies Individually Identifiable Health Information from the data submitted by Practice for individual patients in accordance with the standards set forth in the HIPAA Privacy Rule or to the extent Practice submits information that is not Individually Identifiable Health Information, CDR shall exclusively own such data and information and any derivative works from it, as Intellectual Property Rights owned by CDR.

b. Intellectual Property; Aggregate Data. All Intellectual Property Rights and title to all proprietary information in and rights to any software provided by or used by the CDR in connection with the USWR, including the Registry, all CDR databases and the information contained in such databases, the USWR, any de-identified aggregated data submitted and

accepted by CDR for use in the Registry or developed by the CDR from Individually Identifiable Health Information submitted by Practice pursuant to this Agreement and de-identified of all patient identifiers, and any derivative works prepared by or for the CDR from all of the foregoing including, without limitation, any reports, calculations and models based thereon including without limitation all copyrights, patent rights, trademarks, trade secret rights, and any other rights and interest in any of the foregoing shall be and remain at all times for all purposes with CDR. For purposes of this Agreement, "Intellectual Property Rights" means and includes all, or any intermediate version or portion, of any formulas, processes, outlines, algorithms, ideas, inventions, know how, techniques, intangible, proprietary and industrial property rights and all intangible and derivative works thereof, including without limitation any and all now known or hereafter existing, in and to (i) trademarks, trade name, service marks, slogans, domain names, uniform resource locators or logos; (ii) copyrights, moral rights, and other rights in works of authorship, including, but not limited to, compilations of data, (iii) patents and patent applications, patentable ideas, inventions and innovations; (iv) know-how and trade-secrets; and (v) registrations, applications, renewals, extensions, continuations, divisions or reissues of the foregoing. CDR reserves the right to use de-identified data and protected health information ("PHI") in electronic or other format whether or not contained in a Limited Data Set as discussed more fully in the Business Associate Agreement, including without limitation to support ongoing improvements and enhancements to the Registry. Once the Practice data is accepted by CDR into the Registry for analysis and reporting, this data becomes part of the Registry aggregate data and it cannot be retracted from the Registry by Practice. Information to which CDR has ownership under this Section 5 shall not be considered Confidential Information to be returned to Practice under Section 10.

c. Publication. If Practice desires to publish or otherwise distribute or use, in whole or in part, any aggregate data or reports provided by CDR or produced in connection with or derived from Registry, with the exception of strictly internal use within the Practice for quality assurance and improvement as defined in Section 1, Practice must first obtain the prior express written consent of CDR, which may be granted or withheld in the sole discretion of CDR. To the extent Practice is permitted to publish aggregate data, such aggregate data and any related information published in connection with it must be reviewed and approved by CDR prior to publication.

d. Disclosure of Aggregate Data to Third Parties. Notwithstanding the provisions of this Agreement covering disclosure of data to third parties, the Parties acknowledge that the CDR has the right to disclose aggregate results of the Registry to third parties. All disclosures of such aggregate results must be fully de-identified of all patient, physician, or Practice identifiers.

6. Modifications.

a. Registry Operations. Practice acknowledges that the Registry is a newly developed service of CDR and, as such, may be subject to modification or adjustment by CDR. Practice agrees that CDR may, from time-to-time, modify or amend the substantive provisions of this Agreement related to the manner in which the Registry operates, so long as such modifications or amendments are of general applicability to all similarly situated Practices participating in the Registry. Practice will be bound by any modifications or amendments to this Agreement unless, within thirty (30) days of receipt of such modification or amendment, Practice notifies CDR pursuant to Section 12 of this Agreement that a specific modification or amendment is not acceptable to it, in which case, this Agreement and Practice's participation in the Registry will terminate effective at the end of the thirty (30) day period in which CDR receives such notice. In addition, during the foregoing pre-termination period, Practice shall not have the right to submit further data to the Registry but the other provisions of this Agreement shall apply.

b. IRB Oversight. In the event the Registry is subject to the jurisdiction of an Institutional Review Board ("IRB"), this Agreement, including Practice's responsibilities hereunder, may be amended by CDR on notice to Practice to conform to the requirements of the IRB. CDR will disclose the IRB utilized for review and the findings of such review to Practice upon request.

7. Privacy Laws; Security.

a. Compliance with Privacy Laws. The Parties agree to abide by all federal, state and local laws pertaining to confidentiality and disclosure of any and all information or records obtained and reviewed hereunder. CDR acknowledges that it is performing a function or activity on behalf of Practice, specifically quality assessment and improvement activities as set forth in 45 CFR § 164.501 “Health Care Operations” which involves use, creation and / or access by CDR to Individually Identifiable Health Information of Practice and is therefore a “Business Associate” of Practice, as defined and referred to under HIPAA. Accordingly, CDR shall take reasonable steps to comply with the requirements under HIPAA for Business Associates as set forth in Appendix A to this Agreement (“Business Associate Agreement”). CDR will have all rights, as well as all responsibilities, set forth in Appendix A as if fully set forth herein.

b. Security. CDR will take reasonable steps to maintain security policies and procedures to protect Practice data as provided in Appendix A. If CDR determines that a breach of security has occurred, CDR will notify Practice promptly. CDR will be responsible for its acts and omissions regarding the privacy and security of the data it maintains under this Agreement. In addition to the indemnification provided in Section 11.a., CDR will indemnify, defend, and hold Practice harmless from any third party claim, demand, cause of action, lawsuit or proceeding brought against Practice that are the result of CDR’s acts or omissions regarding the privacy and security of the data it maintains under this Agreement. This indemnification responsibility will be handled consistent with the terms and conditions described in Section 11.a. CDR shall carry adequate liability insurance for acts and omissions under this provision.

8. Use of Names and Logos.

a. Use of CDR or USWR Name. Without the express prior written consent of CDR, Practice shall not make any announcements concerning the matters set forth in this Agreement, use the acronym or symbol CDR or USWR®, or any trademarks or service marks of CDR and CDR’s business partners, or make any reference to CDR or CDR’s business partners in any advertising or promotional material, letterhead, symbol or logo, or other communication that is not strictly internal to Practice, or in any other manner, including, without limitation, press releases or lists. Provided however, Practice may publicly acknowledge that they are a participant in the Registry.

b. Use of Practice’s Logo / Trademarks. Without the express prior written consent of Practice, CDR shall not use the logos, trademarks or service marks of Practice, or make any reference to the Practice in any advertising or promotional material, or other communication that is not strictly internal to CDR, or in any other manner, including, without limitation, press releases or lists.

9. Term, Enforcement and Termination. This Agreement shall be effective for twelve months after the Effective Date noted on the Data Collection Agreement Cover Page. Thereafter it shall renew automatically for additional one (1) year terms unless the either Party provides the other with ninety (90) days advance written notice of its desire to terminate the Agreement at the end of the then current term.

a. Termination for Breach. Either Party may terminate this Agreement upon the other Party’s material breach of this Agreement by providing the non-breaching Party with written notice of its intention to terminate for a material breach. The breaching Party shall have thirty (30) days from receipt of such notice to cure the breach. If, after the foregoing thirty (30) day period, the breach is not cured to the satisfaction of the non-breaching Party, this Agreement shall terminate automatically effective at the end of the thirty (30) day cure period. Notwithstanding the foregoing, the non-breaching Party may determine, in its sole discretion that the breach cannot be reasonably cured within the foregoing thirty (30) day period and may extend the cure period by written notice to the breaching Party.

b. Termination Without Cause. Either Party may terminate this Agreement without cause or penalty by providing the other with at least ninety (90) days written notice, provided that any such termination by Practice shall be effective at the end of the calendar quarter in which CDR receives the notice.

c. Termination for Failure to Meet Data Completeness and Consistency Requirements. CDR reserves the right to immediately terminate this Agreement and Practice’s participation in Registry if it determines that, the Practice’s data

submission for any two (2) calendar quarters within a rolling twelve (12) calendar year is noncompliant with Registry data quality requirements or otherwise unacceptable for inclusion in the Registry national averages. CDR may, in its sole discretion, provide the Practice with the opportunity to cure the inadequate data as stated in Section 3.g. without affecting CDR's rights to terminate this Agreement under this Section or otherwise.

10. Confidentiality.

a. Confidentiality. For the purposes of this Agreement, "Confidential Information" means any software, material, data or business, financial, operational, customer, vendor and other information disclosed by one Party to the other, specifically including, without limitation, the terms of this Agreement and the reports or other benchmarking / quality assurance or improvement data or information furnished by CDR to Practice pursuant to this Agreement. Each Party shall maintain all of the other Party's Confidential Information in strict confidence and will protect such information with the same degree of care that such Party exercises with its own Confidential Information, but in no event with less than a reasonable degree of care. Except as provided in this Agreement, a Party shall not use or disclose any Confidential Information of the other Party in any manner without the express prior written consent of such Party. Access to and use of any Confidential Information shall be restricted to those employees and persons within a Party's organization with known discretion and with a need to use the information to perform such Party's obligations under this Agreement. A Party's consultants, subcontractors and business partners shall be included within the meaning of "persons within a Party's organization," provided that such consultants, subcontractors and business partners have executed a non-disclosure or confidentiality agreement with provisions no less stringent than those applicable to such Party under this Agreement, and such Party shall make such signed agreements available to the other Party upon request. Notwithstanding anything herein to the contrary, Confidential Information shall not include information that is: (a) already known to or otherwise in the possession of a Party at the time of receipt from the other Party and that was not known or received as the result of violation of any obligation of confidentiality; (b) publicly available or otherwise in the public domain prior to disclosure by a Party; (c) rightfully obtained by a Party from any third party having a right to disclose such information without restriction and without breach of any confidentiality obligation by such third party; (d) developed by a Party independent of any disclosure hereunder, as evidenced by detailed written records made in the normal course of Practice's business during the development process; or (e) disclosed pursuant to the order of a court or administrative body of competent jurisdiction or a government agency, provided that the Party receiving such order shall notify the other prior to such disclosure and shall cooperate with the other Party in the event such Party elects to legally contest, request confidential treatment, or otherwise avoid such disclosure.

b. Return of Confidential Information. Except as otherwise provided herein, all of a Party's Confidential Information disclosed to the other Party, and all copies thereof, shall be and remain the property of the disclosing Party. All such Confidential Information and any and all copies and reproductions thereof shall, upon the expiration or termination of this Agreement for any reason, or within fifteen (15) days of written request by the disclosing Party, be promptly returned to it, or destroyed, at the disclosing Party's direction. In the event of such requested destruction, the Party receiving such request shall provide to the other Party written certification of compliance therewith within fifteen (15) days of such written request. Notwithstanding the provisions of this Section 10, any information governed by Section 8.a. or 8.b. or the provisions of the Business Associate Agreement shall be governed, respectively, by those Sections of this Agreement, as applicable.

c. Equitable Relief. The Parties agree that the provisions of this Section 10 are reasonable and necessary to protect the business, interests and properties of each of the Parties; that any breach or threatened breach of this Section 10 by the Party that receives Confidential Information is a material breach of this Agreement which would cause irreparable injury to the Party that disclosed the Confidential Information; and that the disclosing Party's remedy at law for any such breach would be inadequate. Accordingly, each Party agrees that temporary and permanent injunctive relief may be granted in any proceeding which may be brought to enforce any provision of Section 10 without necessity of proof that a remedy at law is inadequate; provided, however that nothing contained herein shall be deemed to preclude the disclosing Party from seeking damages or any other remedy at law or in equity, including compensatory and punitive damages, as may be appropriate, for a breach of this Section 10 by the recipient Party. In addition to the foregoing, any breach or threatened breach of this Section 10 shall be grounds for termination of this Agreement for cause pursuant to Section 9.a. of this Agreement.

11. Indemnification.

a. CDR Indemnity. CDR will indemnify, defend, and hold Practice harmless from any third party claim, demand, cause of action, lawsuit or proceeding brought against Practice based upon any gross negligence or willful misconduct on the part of CDR. Such indemnification may include: (1) reasonable attorneys' fees and costs associated with defense of such claim; (2) damages and costs finally awarded; and (3) the cost of any settlement entered into by CDR. Such indemnification obligation is contingent on Practice (i) notifying CDR of any such claim within thirty (30) days of Practice's notice of such claim, (ii) providing CDR with reasonable information, assistance and cooperation in defending the lawsuit or proceeding (to the extent requested by CDR), and (iii) giving CDR full control and sole authority over the defense and settlement of such claim. CDR will not enter into any settlement or compromise of any such claim without Practice's prior consent, which shall not be unreasonably withheld.

b. Practice Indemnity. Practice will indemnify, defend, and hold CDR harmless from any third party claim, demand, cause of action, lawsuit or proceeding brought against CDR based upon any gross negligence or willful misconduct on the part of Practice. Such indemnification may include: (1) reasonable attorneys' fees and costs associated with defense of such claim; (2) damages and costs finally awarded; and (3) the cost of any settlement entered into by Practice. Such indemnification obligation is contingent on CDR (i) notifying Practice of any such claim within thirty (30) days of CDR's notice of such claim, (ii) providing Practice with reasonable information, assistance and cooperation in defending the lawsuit or proceeding (to the extent requested by Practice), and (iii) giving Practice full control and sole authority over the defense and settlement of such claim. Practice will not enter into any settlement or compromise of any such claim without CDR's prior consent, which shall not be unreasonably withheld.

12. Notices. All notices and demands of any kind or nature which either Party to this Agreement may be required or may desire to serve upon the other in connection with this Agreement shall be in writing, and may be served personally, by registered or certified United States mail, or by overnight courier (e.g., Federal Express, DHL, or UPS) or by e-mail to the following addresses:

If to Practice:	The address on the Cover Page
If to CDR:	Chronic Disease Registry, Inc. 2700 Research Forest Drive, Suite 100 The Woodlands, Texas 77381 Attn: Senior Director, USWR, and General Counsel

Service of such notice or demand so made shall be deemed complete on the day of actual delivery. Any Party hereto may, from time to time, by notice in writing served upon the other Party as aforesaid, designate a different mailing address or a different person to which all further notices or demands shall thereafter be addressed.

13. Sponsorship, Information To Sponsors, and No Obligation to Refer. Practice acknowledges that CDR will receive financial and other support for the operation of the Registry from third parties, including but not limited to pharmaceutical manufacturers ("Sponsors"). Practice hereby consents to the provision by CDR to Sponsors of information derived from information provided by Practice, to the extent required by CDR's agreements with Sponsors, provided that CDR will not furnish information that identifies any individual patient or Practice or any physician affiliated with Practice. Nothing in this Agreement shall be construed to require any physician with the Practice to refer patients or order the products of a Sponsor. Physicians associated with Practice shall at all times use their own individual medical judgment in the best interests of patients of the Practice in the selection of products or services for patients. Neither Party will knowingly or intentionally conduct itself in such a manner as to violate the prohibition against fraud and abuse in connection with the Medicare and Medicaid programs (42 U.S.C. § 1320a-7b) or the physician self-referral law, commonly known as Stark II (42 U.S.C. § 1395nn)].

14. Headings. The headings of the various paragraphs hereof are intended solely for the convenience of reference and are not intended for any purpose whatsoever to explain, modify, or place any construction upon any of the provisions of this Agreement.

15. Assignment. Neither this Agreement nor either Parties' rights and obligations hereunder may be assigned to a third party without the prior written consent of the non-assigning Party.

16. Relationship of Parties. The relationship of the Parties to this Agreement is that of independent contractors and not that of master and servant, principal and agent, employer and employee, or partners or joint ventures.

17. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which taken together shall constitute one and the same instrument.

18. Waiver. A waiver by either Party to this Agreement of any of its items or conditions in any one instance shall not be deemed or construed to be a general waiver of such term or condition or a waiver of any subsequent breach.

19. Severability. All provisions of this Agreement are severable. If any provision or portion hereof is determined to be unenforceable by a court of competent jurisdiction then the rest of the Agreement shall remain in full effect, provided that its general purposes remain reasonably capable of being effected.

20. Entire Agreement. This Agreement and the attached Appendices (a) constitute the entire Agreement between the Parties with respect to the subject matter; (b) supersede and replace all prior agreements, oral or written, between the Parties relating to the subject matter; and (c), except as otherwise indicated, may not be modified or otherwise changed in any manner except by a written instrument executed by both Parties. Notwithstanding the foregoing, where this Agreement specifically provides for amendment, revision or updating by the CDR of this Agreement or of any document referred to in this Agreement or incorporated by reference into this Agreement, Practice will be advised of such amendments or updates by email to Practice at the address specified in Section 3.c. and Practice will be bound when the amendment or update is emailed by the CDR. Except as specifically stated in this Agreement, such amendment, revision, or updating shall not confer any right in Practice to terminate this Agreement.

21. Survival. The following sections of this Agreement survive its termination, for any reason: Sections 5, 7, 8, 10, 11, 18 and the Business Associate Agreement.

22. No Third Party Beneficiaries. The Parties agree that there are no third party beneficiaries, intended or otherwise, to this Agreement, including without limitation, patients of any Practice.

[END OF MASTER TERMS]