

**To obtain a Registry Participation Agreement for your organization,
please contact us at rcr@rheumatology.org**

REGISTRY PARTICIPATION AGREEMENT

This Registry Participation Agreement, including its exhibits and attachments, (this “**Agreement**”) is entered into this ___ day of _____, 200__ (“**Effective Date**”), by and among (i) Outcome Sciences, Inc. d/b/a Outcome, a Delaware corporation with its principal place of business at 201 Broadway, Cambridge, Massachusetts 02139 (“**Outcome**”), (ii) American College of Rheumatology, an Illinois not-for-profit corporation with its principal place of business at 2200 Lake Boulevard NE, Atlanta, Georgia, 30319 (“**ACR**”) and (ii) _____, [**IF ENTITY:** a[n] _____] with its principal place of business at _____] [**IF INDIVIDUAL:** an individual residing at _____] (“**Participant**”; Outcome, ACR and Participant collectively, the “**Parties**” and each individually, a “**Party**”).

WHEREAS, Outcome and ACR have entered into a certain Data Collection and Database Services Agreement dated July 31, 2007 (as the same may be amended or otherwise modified from time to time, the “**DCDSA**”), pursuant to which Outcome and ACR have developed a practice-based clinical data management tool known as the Rheumatology Clinical Registry (the “**Registry**”) using Outcome’s proprietary system that collects and reports on clinical data (the “**Outcome Technology**”);

WHEREAS, the Registry provides a mechanism that will enable Participant to access its own data and analyses of Participant’s data, and compare such data and analyses with aggregated provider and/or practice performance data in specific areas covered by the Registry and similar national and regional summary performance data, in order to advance Participant’s quality improvement initiatives;

WHEREAS, pursuant to the DCDSA, ACR owns the Registry and Outcome is responsible for developing and operating the Registry;

WHEREAS, adequate facilities and expertise are available to Participant for Participant to participate in the Registry;

WHEREAS, Participant desires to participate in the Registry, to improve the quality of care it provides to its patients with rheumatologic conditions, by contributing certain data to the Registry and receiving access to and use of the Registry, via the Outcome Technology, as set forth in this Agreement; and

NOW, THEREFORE, in consideration of the mutual covenants and promises herein contained, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows.

1. **Participation in and Use of the Registry by Participant**

(a) Participant agrees to participate in the Registry in accordance with the terms and conditions of this Agreement.

(b) In conducting and participating in the Registry, Participant shall comply with the terms, conditions and obligations outlined in this Agreement and the data collection procedures established by Outcome and ACR with regard to the Registry.

(c) Outcome and ACR shall grant Participant access to the de-identified and aggregated data contained in the Registry via the Registry benchmarking reports, for individual practice enhancement, practice quality measurement, quality reporting, maintenance of specialty board certification and for such other uses as are set forth from time to time in the Policy and Guidelines, as defined in Section 5(e) and attached hereto as Exhibit A.

(d) Outcome and Participant acknowledge and agree that ACR shall have access to the data submitted to Outcome by Participant and by other participants in the Registry that has been de-identified and/or aggregated, provided that ACR shall not have access to any PHI (as defined in Section 2(b)) except as expressly set forth in Section 2(c).

(e) All fees payable to Outcome in connection with Participant's participation in the Registry to support practice improvement shall be paid by ACR to Outcome. The parties acknowledge and agree that the foregoing does not apply to any fees associated with PQRI reporting services, and that any fees payable to Outcome in connection with such services, shall be paid in accordance with the terms and conditions of the applicable agreement or other arrangement for such services.

2. **Regulatory Compliance.**

(a) Participant shall comply with all applicable federal, state and local laws, regulations and guidelines including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") and the Privacy Rule promulgated thereunder at 45 C.F.R. Parts 160 and 164 ("**Privacy Rule**"), as well as any such laws, regulations or guidelines concerning human research to the extent applicable.

(b) Outcome and Participant acknowledge and agree that the data received by Outcome from Participant pursuant to Section 1 hereof will consist, in whole or in part, of "protected health information," as that term is defined at 45 C.F.R. § 160.103 ("**PHI**"). Accordingly, Participant and Outcome shall enter into a Business Associate Agreement (the "**BAA**") in the form attached hereto as Exhibit B.

(c) Outcome, Participant and ACR acknowledge and agree that Outcome, in its capacity as a business associate of Participant, may disclose to ACR, on behalf of Participant, and ACR may use and disclose, certain PHI in the form of a "limited data set," as that term is defined at 45 C.F.R. § 164.514(e) ("**LDS**"). Accordingly, ACR and Participant shall enter into a Data Use Agreement (the "**Data Use Agreement**") in the form attached hereto as Exhibit C.

3. **Term and Termination**

(a) Participant's participation in the Registry shall commence on the Effective Date and will continue until the earlier of (i) the date when ACR discontinues the Registry or (ii) the date this Agreement is terminated pursuant to Section 3(b), Section 3(c) or Section 3(d).

(b) This Agreement may be terminated by the Participant upon five (5) business days prior written notice to Outcome in the event that Outcome breaches any provision of Exhibit A and such breach is not cured within such five (5) business day period.

(c) Participant or ACR may terminate this Agreement at any time for any reason by providing ten (10) days' prior written notice to the other Party and to Outcome of its intent to terminate the Agreement.

(d) This Agreement may be terminated by Outcome immediately upon written notice to ACR and Participant in the event that (i) ACR or Participant breach any material provision of this Agreement and such breach is not cured within a five (5) business day period; or (ii) the DCDSA expires, terminates or is terminated.

4. **Limitation of Liability**

Outcome, ACR and Participant each hereby agree that in no event will any Party be liable to any other Party for consequential, indirect, incidental, punitive, or any other non-direct damages including, without limitation, lost profits or any claim or demand against a Party by any other Party due to any cause whatsoever, even if such other Party has been advised of the possibility of such damages.

5. **Ownership of and Rights of Parties in Data.**

(a) Definitions. For purposes of this Agreement:

(i) **“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;

(ii) **“ACR IP”** means the Intellectual Property Rights of ACR; and

(iii) **“Outcome IP”** means the Intellectual Property Rights of Outcome.

(b) Participant Data. Patient data submitted by Participant (**“Participant Data”**) shall be the exclusive property of Participant, subject to the rights, if any, of the patients of Participant in such information, and subject to the rights granted to ACR and Outcome in this Agreement, the Business Associate Agreement and the Data Use Agreement. Participant hereby acknowledges and agrees that the return or destruction of Participant Data is infeasible, as such Participant Data will have been inextricably integrated into the Registry. Participant hereby grants to ACR and Outcome a perpetual, enterprise-wide, royalty-free license, that is worldwide

and in all forms and all media (including derivative works), to use the Participant Data pursuant to the terms and conditions of this Agreement.

(c) Outcome IP.

(i) The relative rights and obligations of Outcome and ACR with respect to Outcome IP shall be governed by the DCDSA.

(ii) Participant agrees that the Outcome System® platform and all intellectual property or inventions which are related to Outcome System® platform, arise out of, or are developed by Outcome in connection with Outcome System® platform consist of Outcome IP and is the exclusive property of Outcome and its suppliers and all ownership rights in Outcome System® platform shall vest solely in Outcome and/or its suppliers. Participant further acknowledges and agrees that Outcome IP further consists of certain inventions, processes, know-how, trade secrets, improvements, other intellectual properties and other assets of Outcome, including but not limited to analytical methods, procedures and techniques, procedure manuals, personnel data, financial information, computer technical expertise and software, which have been independently developed by Outcome which relate to its business or operations. Participant agrees that it shall acquire no Intellectual Property Rights in any of Outcome IP. Participant further agrees that any improvements, modifications or derivatives to Outcome IP which are developed under or during the term of this Agreement are the sole and exclusive property of Outcome, but only to the extent that such improvements, modifications or derivatives are not intrinsic to, or derived from ACR IP, information or specimens. Participant shall not, in whole or in part, modify, translate, decompile, disassemble, reverse engineer or distribute Outcome IP.

(d) ACR IP.

(i) The relative rights and obligations of Outcome and ACR with respect to ACR IP shall be governed by the DCDSA.

(ii) Participant agrees that all Intellectual Property Rights in and title to all proprietary information in and rights to any software provided by ACR in connection with the Registry, all ACR databases and the information contained in such databases, any de-identified aggregated data submitted to and accepted by Outcome for use in the Registry or developed by Outcome from data submitted by Participant pursuant to this Agreement or the DCDSA and de-identified of all patient identifiers, and any derivative works prepared by or for ACR 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 ACR.

(iii) To the extent Outcome de-identifies PHI from the data submitted by Participant for individual patients in accordance with the standards set forth in the Privacy Rule, such data and information and any derivative works therefrom shall be ACR IP.

(e) Disclosure of Aggregate Data to Third Parties. Notwithstanding the provisions of this Agreement covering disclosure of data to third parties, the parties acknowledge that ACR has the right to disclose aggregate results of the Registry to third parties, including without limitation other Registry participants. Access to the Registry and the use and disclosure of the data contained in the Registry shall at all times be consistent with the Policy and Guidelines attached hereto as Exhibit A.

6. **Miscellaneous**

(a) No press release, advertising, promotional sales literature or other promotional written statements or promotional oral statements to the public in connection with or alluding to work performed under this Agreement or the relationship between any of the parties created by it, having or containing any reference to any Party to this Agreement, or the name of any member of such Party's staff, shall be made by any other Party without the prior written approval of such Party.

(b) The termination or expiration of this Agreement shall not relieve the obligations undertaken by the parties in Sections 2 and 4. Any other provisions of this Agreement that by their nature are intended to survive termination or expiration of this Agreement shall so survive.

(c) This Agreement and all exhibits and attachments hereto constitute the entire agreement among the parties with respect to the subject matter hereof (other than the DCDSA), and all prior negotiations, representations, agreements and understandings are superseded hereby. No agreements amending, altering or supplementing the terms hereof may be made except by means of a written document signed by the duly authorized representatives of the parties.

(d) Any notice required by this Agreement shall be given by (i) prepaid, first class, certified mail, return receipt requested, (ii) overnight courier service, or (iii) confirmed facsimile to the parties at their addresses set forth above.

(e) This Agreement shall be governed and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to conflict of law principles.

(f) The invalidity or unenforceability of any term or provision hereof shall not affect the validity or enforceability of any other term or provision hereof. All terms and covenants contained herein are severable, and if any of the provisions hereof shall be held to be invalid or unenforceable by a competent court, this Agreement shall be interpreted as if such invalid or unenforceable term or covenant were not contained herein.

(g) No failure to exercise any right or demand performance of any obligation under the Agreement shall be deemed a waiver of such right or obligation.

(h) This Agreement may be executed by facsimile or other electronic format (including, without limitation, PDF) and in one or more counterparts, each one of which shall be deemed an original.

(i) For the purposes of this Agreement, the parties shall be deemed to be independent contractors and not employees or agents of the other.

(j) This Agreement may not be assigned by Participant without the prior written approval of ACR and Outcome.

(k) This Agreement shall be binding upon and inure to the benefit of each of the parties hereto and their successors and permitted assigns.

[Signature Page Follows]

SAMPLE

IN WITNESS WHEREOF, the parties have executed this Agreement by their duly authorized representatives on the dates set forth below effective on the date first above written.

PARTICIPANT: [_____]

By: _____
Name: _____
Title: _____

ACR: **AMERICAN COLLEGE OF RHEUMATOLOGY,**
an Illinois not-for-profit corporation

By: _____
Name: _____
Title: _____

OUTCOME: **OUTCOME SCIENCES, INC.,** a Delaware
corporation, d/b/a Outcome

By: _____
Name: _____
Title: _____

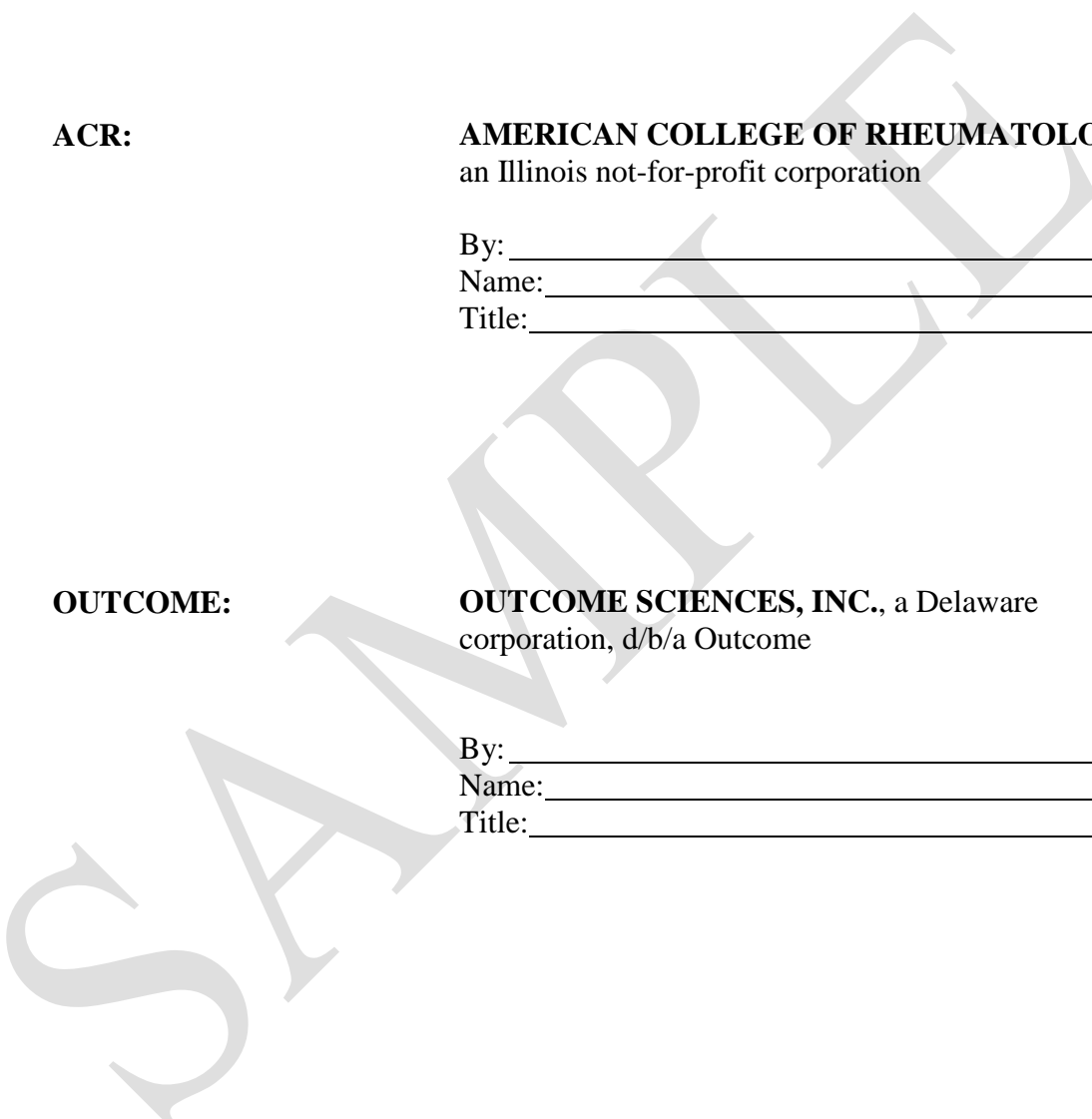


EXHIBIT A

**POLICY AND GUIDELINES FOR ACCESS TO AND USE OF DATA FROM THE
AMERICAN COLLEGE OF RHEUMATOLOGY CLINICAL REGISTRY**

(Attached)

SAMPLE

American College of Rheumatology

Policy and Guidelines for Access to and Use of Data from the American College of Rheumatology Rheumatology Clinical Registry (“RCR”)

The interests of the public and the medical profession are best served when scientifically sound and unbiased data and resources are made available to the physician and healthcare community. The purpose and goal of establishing the American College of Rheumatology Rheumatology Clinical Registry (the “ACR Registry”) is to engage in the process of collecting data from clinicians and utilize such data to enhance and support the clinical decision-making process and to improve the quality and efficiency of care delivered to rheumatology patients. The American College of Rheumatology (“ACR” or the “College”) believes that the adoption of these guidelines will help further that objective.

These guidelines will provide information on the specific and accepted professional and third party access to and use of data and database-derived information from the ACR Registry. Adherence to these guidelines and accurate reporting of the data is important to the meaningfulness of the ACR Registry.

I. Sources of Data, Ownership of Data, and Potential Uses of Data

A. Rheumatologists, other individual healthcare providers and institutions (each a “Participant” and collectively, the “Participants”) will submit clinical data to an independent data warehouse service provider (“Service Provider”) who will de-identify the data and send such de-identified data to the Registry (the “Data”). The Data will be de-identified in accordance with the requirements of 45 C.F.R. 164.514 of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). The Data in the Registry may be aggregated pursuant to criteria adopted from time to time by the College.

B. Subject to the rights of patients in their individually identifiable health information, each Participant will own his/her/its own local data submitted to the Service Provider (with respect to such Participant, “Participant Data”); however, such Participant shall have no ownership rights in any Data that is de-identified by the Service Provider and submitted to the ACR Registry. Further, Participant shall not have the right or ability to remove the Participant Data after it is submitted to the Service Provider, de-identified and aggregated in the Registry.

C. The de-identified and/or aggregated Data is the exclusive and sole property of the College. The College will insure that any disclosure, reporting, dissemination or use of the Data by other parties, including participating clinicians, is in compliance with these guidelines.

D. The Data may be used for abstracts, scientific meeting presentations, manuscripts for publication in scientific journals, for education, for individual practice enhancement, for the development of quality measure tools, for practice quality measurement, for maintenance of specialty board certification, for the development of practice guidelines, for

legislative and/or regulatory initiatives, for use by third parties, for the development of position papers and for such other uses as the College in its sole discretion deems appropriate. Any such use would be subject to ACR policy, approval and oversight, as the College deems necessary.

E. All research, publications, position papers and presentations, and participant marketing tools culminating from access to and use of the ACR Registry will require the prior review and approval of the ACR and will acknowledge the College and the Registry as a resource.

II. Participant Use of Data

A. Participant Data in comparison to aggregated national data may be used for clinical research by a Participant; however, to the extent the particular research hypothesis and methods used by the Participant must be evaluated by an appropriate Institutional Review Board (“IRB”), Participant shall be solely responsible for obtaining IRB approval. From such clinical research, a Participant may produce abstracts, scientific meeting presentations, manuscripts and similar educational materials for peer review and dissemination, subject to the prior review and approval of ACR.

B. Participants may use Participant Data for their own quality assurance and monitoring of quality improvement processes. In furtherance thereof, Participants may provide Participant Data to the American Board of Internal Medicine for maintenance of certification purposes and to the Centers for Medicare and Medicaid Services (“CMS”) for physician quality reporting initiatives.

C. Participants may use Participant Data, as tracked by them and/or as reported by the Service Provider for certain limited purposes besides quality assurance and monitoring of quality improvement processes. For example, a Participant may use Participant Data for care delivery activities or monitoring. Pursuant to such care delivery activities, a Participant may report Participant specific statistics and outcomes as part of (i) informing individual referring physicians; (ii) providing patient counseling; and (iii) collaborative work with other rheumatologists and physicians in other medical and surgical specialties.

D. Participants may also use Participant Data as an aid for managed care contract negotiations (e.g., Participants may report their own statistics and outcomes in comparison with the ACR National Registry national mean or average, recognizing that the ACR has not set a minimal threshold).

E. Participants are allowed to report their own statistics and outcomes in comparison with the ACR Registry national or regional mean or average, as a benchmark assessment. The ACR will ensure that regions are large enough so that no individual practitioner or group can be identified. Ideally, such Participant-specific data reporting shall be reported as trends over an extended period of time.

F. Participants may use Participant Data, as tracked by him/her/it/them and/or as reported by the Service Provider to participate in educational or promotional initiatives in which Participant’s Data is compared to the ACR Registry national or regional mean or average. These activities must be pre-approved by the College in writing.

G. Statements made by a Participant regarding his/her/its data or outcomes shall not contain any false or misleading statements and shall in all respects comply with the College's Code of Ethics and all other guidelines established by the College from time to time regarding advertising or promotional efforts by its members.

H. Any reports of noncompliance or questions of impropriety in the use and reporting of any data by a participating rheumatologist may be referred to the College's Ethics Committee.

III. Non-Participating ACR Member Use of Data

A. Members of the College who are not current Participants in the Registry may upon request and ACR approval be given access to the aggregated national data. In the event such approval is granted, such Members of the College must execute the appropriate agreements with the Service Provider prior to having access to the Registry.

B. The purposes for which a non-participating ACR Member may use the aggregated national data will be determined by the College.

IV. Corporate Use of Data

A. Corporate entities in the medical field (e.g., pharmaceutical, manufacturer and medical device companies, investment companies) and insurers may not have direct access to the data but may submit ad hoc queries to the College for data analysis by the Service Provider.

B. The College upon review of any ad hoc inquiries by corporate entities may determine that these inquiries may be useful in furthering the goals and purposes of the ACR Registry. For example, specific product use trends as reported to the ACR Registry may be used for tracking outcomes of newly implemented products, procedures and drugs, and for monitoring the safety and effectiveness of newly implemented products, procedures and drugs.

C. All such inquiries are subject to prior approval by the College, which may be withheld in the College's sole discretion. Such approval shall be in accordance with such procedures and other requirements as the College may establish from time to time and shall require payment of appropriate costs and expenses by the corporate entity.

D. Data analysis and reporting back to the requestor on the product-specific, device-specific or drug-specific utilization will be carried out with appropriate and necessary "blinding," so that the entity can be compared to other similar product, device or drug utilization. If the need arises to compare two different entities, i.e. surgery vs. non-surgical therapies, this too will be done at ACR discretion.

V. Third Party Reports

A. The College in its sole discretion may arrange for the generation of special reports requested by third parties (e.g., pharmaceutical, manufacturer and medical device companies, insurers, investment companies).

B. Requests for reports for a third party will be evaluated separately and in accordance with the restrictions imposed by the College on the use of database-derived information. Such reports shall require the payment of appropriate costs and expenses by the requesting party.

C. The College will enter into written agreements with each third party to whom or to which it agrees to provide a report. These agreements will govern the permissible use of the report.

VI. ACR Use of Data

The ACR may access and use the de-identified aggregated data on a national, state or regional basis to generate reports addressing the quality of rheumatology care in a specific region or area, to focus on a specific quality of care issue, or to focus on quality of care or practice trends. It is understood that ACR has no access to or ability to access individual Participant Data and may not use the de-identified and aggregated data to address the performance of individual Participants in the Registry. The College may also use de-identified aggregated data from the Registry for legislative and/or regulatory initiatives with the ultimate goal of improving the quality of patient care. The College may access and use the de-identified aggregated data for such other purposes as it deems appropriate with the goal of promoting quality care improvements in the field of rheumatology.

VII. Physical Procedures Regarding Data Access

A. The Data will be secured using industry-standard physical and procedural security safeguards to prevent loss or unauthorized access to the Data.

B. Any known security breaches will be reported to the applicable agency, authority or individual as required by applicable law or agreement.

VIII. Summary

The College, all Participants and all recipients of the Data have significant responsibilities in ensuring that the ACR Registry works fairly for all Participants and other recipients of the Data. The College and each Participant and third-party entities are responsible for appropriate use of the ACR Registry data per their individual contracts. Each Participant is encouraged to use the Data and in particular his/her/its/their Participant Data to improve the quality of care delivered to patients of Participants. The College as the owner of the aggregated Data has the responsibility to make the Data available to promote quality care improvements in the field of rheumatology and to improve patient health and safety, as feasible.

EXHIBIT B

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (this “**BAA**”) is by and among Outcome Sciences, Inc. d/b/a Outcome, a Delaware corporation with its principal place of business at 201 Broadway, Cambridge, Massachusetts 02139 (“**Outcome**”) and _____, [**IF ENTITY:** a[n] _____ with its principal place of business at _____] [**IF INDIVIDUAL:** an individual residing at _____] (“**Participant**”).

1. Outcome, Participant and American College of Rheumatology are party to a certain Registry Participation Agreement (the “**Registry Agreement**”). Terms used and not otherwise defined in this BAA shall have the meanings ascribed to such terms under the Health Insurance Portability and Accountability Act of 1996 and regulations promulgated thereunder at 45 C.F.R. Parts 160, 162 and 164 (as amended from time to time, collectively, “**HIPAA**”).

2. This BAA shall be effective as of the Effective Date of the Registry Agreement.

3. Pursuant to the Registry Agreement, Participant has agreed to furnish certain data to Outcome for inclusion in the Registry (such data, the “**Data Set**”).

4. The parties acknowledge that Data Set may contain Protected Health Information (“**PHI**”) subject to the requirements of HIPAA. Outcome agrees to use and/or disclose Data Set PHI (as defined below) only as permitted or required by this BAA or as otherwise required by law and, notwithstanding any other provisions of this BAA or the Registry Agreement, Outcome shall not use or disclose Data Set PHI obtained pursuant to the Registry Agreement in a manner that would violate state or federal law.

5. Data Set. Participant agrees that the PHI that will be disclosed to Outcome shall consist only of the data elements specified in Attachment A-1 (the PHI and the Data Set shall be referred to as the “**Data Set**”) for health care operations purposes on behalf of Participant, including de-identifying/aggregating the Data Set (“**Business Associate Purposes**”). Outcome agrees to use those data elements that are contained in the Data Set only for Business Associate Purposes in compliance with the provisions of Sections 6 through 18 of this BAA.

6. Use of Data. Outcome may use and disclose the Data Set only as permitted under the terms of this BAA or as required by law, but shall not otherwise use or disclose the Data Set, and shall ensure that its directors, officers, employees, contractors and agents do not use or disclose the Data Set in any manner that would constitute a violation of HIPAA if used or disclosed by Participant. Outcome shall limit the use or receipt of the Data Set to the individuals employed or engaged by Outcome who need the Data Set for the performance of the Business Associate Purposes.

7. Minimum Necessary Information. Outcome represents that, to the extent Outcome requests Participant disclose the Data Set to Outcome hereunder such a request will only be for the minimum data necessary to accomplish the Outcome Purposes of the request.

8. Safeguards Against Misuse of Information. Outcome will use appropriate safeguards to prevent the use or disclosure of the Data Set except as permitted under this BAA or as permitted or required by law.

9. Reporting of Disclosures of PHI. Outcome shall, within fifteen (15) days of becoming aware of any use or disclosure of the Data Set in violation of this BAA by any of its officers, directors, employees, contractors or agents or by a third party to which Outcome discloses the Data Set report to Participant any such disclosure.

10. Agreements by Third Parties. Business associate shall obtain and maintain an agreement with each agent or subcontractor (“**Subcontract**”) that has or will have access to the Data Set through Outcome, pursuant to which such agent or subcontractor shall agree to be bound by the same restrictions, terms and conditions that apply to Outcome under these Requirements with respect to the Data Set. Outcome, however, shall not be required to enter into a Subcontract with a third party to which Outcome discloses the Data Set, on Participant’s behalf, if Participant has already entered into a business associate agreement with that third party.

11. Notice of Request for Data. Outcome agrees to notify Participant within five (5) business days of Outcome’s receipt of any request for production or subpoena of the Data Set received from Participant, in connection with any governmental investigation or governmental or civil proceeding. If Participant decides to challenge the validity of or assume responsibility for responding to such request or subpoena, Outcome shall cooperate fully with Participant in connection therewith.

12. Return or Destruction of Data. The terms and provisions of these Requirements that protect PHI in the Data Set shall survive termination of the Registry Participation Agreement and such information shall thereafter only be used or disclosed for Outcome Purposes, as applicable.

13. Access to Information. If any individual makes a written request to Outcome seeking access to the Data Set maintained by Outcome, Outcome shall, within five (5) days of receipt of such request forward such request to Participant. Any denial of access to the Data Set shall be the sole responsibility of Participant. If any individual requests Participant to provide access to the Data Set maintained by Outcome, then within ten (10) days of a corresponding request to Outcome by Participant for access to such Data Set, Outcome shall provide Participant with such data or information.

14. Availability of PHI for Amendment. If any individual makes a written request to Outcome seeking to amend information in the Data Set maintained by Outcome, then Outcome shall, within five (5) days of receipt of such request, forward such request to Participant. If Outcome receives a written request from Participant to amend information in the Data Set maintained by Outcome, then within ten (10) days of receipt of such request from Participant, Outcome shall provide such information to Participant for amendment, and upon written direction by Participant shall incorporate any such amendments in the Data Set as required by HIPAA.

15. Accounting of Disclosures. If any individual requests in writing that Outcome provide an accounting of disclosures of information contained in the Data Set maintained by Outcome, Outcome shall, within five (5) days of the receipt of such request, forward such request to Participant. If any individual requests in writing that Participant provide an accounting of disclosures of information contained in the Data Set maintained by Outcome, then, within ten (10) days of notice by Participant to Outcome that it has received such an accounting request, Outcome shall account to Participant for such disclosures of such Data Set, except that no such accounting shall be required for disclosures of the Data Set for Business Associate Purposes and other disclosures which are not subject to accounting under HIPAA. Where an accounting is required to be provided to Participant by Outcome under these Requirements or the Privacy Rule, Outcome shall provide the following information: (1) the date of the disclosure, (2) the name of the entity or person who received the Data Set, and if known, the address of such entity or person, (3) a brief description of the Data Set disclosed, and (4) a brief statement of the purpose of such disclosure which includes an explanation of the basis for such disclosure. Outcome hereby agrees to implement an appropriate recordkeeping process to enable it to comply with the requirements of this Section.

16. Availability of Books and Records. Outcome hereby agrees to make its internal practices, books and records relating to the use and disclosure of PHI received from, or created or received by Outcome on behalf of Participant available to the Secretary of the United States Department of Health and Human Services for purposes of determining Participant's compliance with HIPAA.

17. Security Rule Provisions Regarding Electronic Protected Health Information. Outcome shall: (1) implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of electronic protected health information that it creates, receives, maintains, or transmits on behalf of Participant; (2) ensure that any agent, including a subcontractor, to whom it provides electronic protected health information agrees to implement reasonable and appropriate safeguards to protect such electronic protected health information; and (3) as commercially reasonable, report to Participant any security incident (as such term is defined in HIPAA) of which it becomes aware.

18. Breach Notification: Unsecured PHI. Outcome shall notify Participant promptly, but no more than sixty (60) days, after Outcome discovers any breach of unsecured PHI (as defined under the Data Breach Notification Rules, 45 CFR §164.400-164.530) to allow Participant to comply with its Breach notification obligations under the Health Information Technology for Economic and Clinical Health Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009. Such notification shall include, to the extent possible, (a) a list of individuals whose unsecured PHI was acquired, accessed, used or disclosed as a result of the Breach, (b) a description of the Breach, (c) the date the Breach occurred, (d) the date the Breach was discovered by Outcome, (e) the categories of PHI involved in the Breach, (f) the status of Outcome's investigation into the Breach, (g) any steps taken by Outcome to mitigate harm with respect to the affected individuals and (h) any steps taken to protect against further Breaches.

19. Obligations of the Participant. Participant hereby agrees: (1) to inform Outcome of any changes in the form of notice of privacy practices (the "**Notice**") that Participant provides

to individuals pursuant to 45 C.F.R. § 164.520, and to provide Outcome a copy of the Notice currently in use; (2) to notify Outcome, in writing and in a timely manner, of any arrangements permitted or required of Participant under HIPAA that may impact in any manner the use and/or disclosure of the PHI by Outcome under this Agreement, including, but not limited to, restrictions on use and/or disclosure of PHI as provided for in 45 C.F.R. § 164.522 agreed to by Participant; (3) to notify Outcome, in writing and in a timely manner, of any statute, regulation, administrative, or judicial ruling pertaining to Participant, including but not limited to federal and state provisions that require Outcome to protect the confidentiality, privacy and/or security of PHI; (4) agree that Outcome may make any use and/or disclosure of PHI permitted under 45 C.F.R. § 164.512; and (5) use reasonable and appropriate safeguards to maintain and ensure the confidentiality, privacy and security of PHI transmitted or received by Participant in accordance with HIPAA.

[Signature Page Follows]

SAMPLE

COVERED ENTITY: [_____]

By: _____

Name: _____

Title: _____

**BUSINESS
ASSOCIATE:**

OUTCOME SCIENCES, INC., a Delaware
corporation, d/b/a Outcome

By: _____

Name: _____

Title: _____

SAMPLE

ATTACHMENT A-1 TO BUSINESS ASSOCIATE AGREEMENT

DATA SET

1. Patient ID number
2. Medical Record Number
3. First Name (and middle initial)
4. Last Name
5. Street Address
6. Telephone Number
7. Email Address

SAMPLE

EXHIBIT C

DATA USE AGREEMENT

This DATA USE AGREEMENT (this "Data Use Agreement") is entered into by and between American College of Rheumatology ("ACR") and _____ ("Participant"). The purpose of this Data Use Agreement is to provide ACR with access to a Limited Data Set ("LDS") for use in its research and analysis activities that support the mission of ACR, in accordance with the Privacy Rule. This Data Use Agreement shall be effective as of the Effective Date of that certain Registry Participation Agreement (the "**Registry Agreement**") between and among Participant, ACR and Outcome Science Inc. ("**Outcome**").

RECITALS

WHEREAS, Participant is a "covered entity" as that term is defined under the Privacy Rule (defined below);

WHEREAS, ACR is the sponsor of the American College of Rheumatology Registry (the "**Registry**");

WHEREAS, the Registry is maintained by Outcome, pursuant to a certain Data Collection and Database Services Agreement dated July 31, 2007 (as the same may be amended or otherwise modified from time to time, the "**DCDSA**");

WHEREAS, pursuant to the Registry Agreement, Participant furnishes certain PHI (defined below) to Outcome, and as such Outcome and Participant have entered into a certain Business Associate Agreement of even date herewith (the "**BAA**");

WHEREAS, the Registry contains data received from clinicians by Outcome, and utilizes such data to assist rheumatologists in improving the quality of care delivered to rheumatology patients on both a national and local level;

WHEREAS, Participant wishes to allow ACR access to a "limited data set," as that term is defined at 45 C.F.R. § 164.514(e), for the purposes of research, public health and health care operations, which limited data set (the "**LDS**") shall include "protected health information," as that term is defined at 45 C.F.R. § 160.103 ("**PHI**") only to the extent it excludes the identifiers listed at 45 C.F.R. § 164.514(e)(2);

WHEREAS, Participant wishes to ensure that ACR will appropriately safeguard the LDS in accordance the Privacy Rule; and

WHEREAS, ACR agrees to protect the privacy of the LDS in accordance with the terms and conditions of this Data Use Agreement, the Participation Agreement the Privacy Rule.

NOW THEREFORE, Participant and ACR agree as follows:

1. **Definitions**. Unless otherwise specified in this Data Use Agreement, all capitalized terms used in this Data Use Agreement not otherwise defined have the meaning

established for purposes of the regulations codified at Title 45 parts 160 through 164 of the United States Code of Federal Regulations, as amended from time to time (the “Privacy Rule”).

2. **Preparation of the LDS.** Outcome, in its capacity as a Business Associate of Participant shall prepare and furnish to ACR the LDS in accordance with the Privacy Rule.

3. **Minimum Necessary Data Fields in the LDS.** In preparing the LDS, Outcome shall include the data fields specified by the parties from time to time, which are the minimum necessary to accomplish the purposes set forth in Section 5 of this Data Use Agreement, but in no event shall include any of the identifiers listed at 45 C.F.R. § 164.514(e)(2);

4. **Responsibilities of ACR.** ACR agrees to:

(a) Use or disclose the LDS only as permitted by this Data Use Agreement or as required by law;

(b) Use appropriate safeguards to prevent use or disclosure of the LDS other than as permitted by this Data Use Agreement or required by law;

(c) Report to Outcome, who shall report to Participant pursuant to the BAA, any use or disclosure of the LDS of which it becomes aware that is not permitted by this Data Use Agreement or required by law;

(d) Require any of its subcontractors or agents that receive or have access to the LDS to agree to the same restrictions and conditions on the use and/or disclosure of the LDS that apply to ACR under this Data Use Agreement; and

(e) Not use the information in the LDS to identify or contact the individuals who are data subjects.

5. **Permitted Uses and Disclosures of the LDS.** ACR may use and/or disclose the LDS for its research and analysis activities that support the mission of ACR and for the Health Care Operations of the Participant.

6. **Term and Termination.**

(a) **Term.** The term of this Data Use Agreement shall commence as of the Effective Date and shall continue for so long as ACR retains the LDS.

(b) **Termination by ACR.** ACR may terminate this Data Use Agreement at any time, subject to the terms of Section 6(e).

(c) **Termination by Participant.** Participant may terminate this Data Use Agreement at any time by providing thirty (30) days prior written notice to ACR.

(d) **For Breach.** Participant shall provide written notice to ACR within ten (10) days of any determination that ACR has breached a material term of this Data Use Agreement. Participant shall afford ACR an opportunity to cure said alleged material breach

upon mutually agreeable terms. Failure to agree on mutually agreeable terms for cure within thirty (30) days shall be grounds for the immediate termination of this Data Use Agreement by Participant.

(e) Effect of Termination. Sections 1, 4, 5, 6(e) and 7 of this Data Use Agreement shall survive any termination of this Data Use Agreement. Participant acknowledges and agrees that returning or destroying the LDS would be not feasible, as the data contained therein will become an inextricable part of the aggregated data contained in the Registry, and accordingly ACR shall continue to extend the protections of this Data Use Agreement to the LDS and limit further use and disclosure of the LDS to those purposes that make the return or destruction of the LDS infeasible.

7. **Miscellaneous.**

(a) Change in Law. The parties agree to negotiate in good faith to amend this Data Use Agreement to comport with changes in federal law that materially alter either or both parties' obligations under this Data Use Agreement. Provided however, that if the parties are unable to agree to mutually acceptable amendment(s) by the compliance date of the change in applicable law or regulations, either party may terminate this Data Use Agreement as provided in Section 6.

(b) Construction of Terms. The terms of this Data Use Agreement shall be construed to give effect to applicable federal interpretative guidance regarding the Privacy Rule.

(c) No Third Party Beneficiaries. Nothing in this Data Use Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.

(d) Counterparts. This Data Use Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

(e) Headings. The headings and other captions in this Data Use Agreement are for convenience and reference only and shall not be used in interpreting, construing or enforcing any of the provisions of this Data Use Agreement.

[Signature Page Follows]

PARTICIPANT: [_____]

By: _____

Name: _____

Title: _____

ACR: **AMERICAN COLLEGE OF RHEUMATOLOGY**

By: _____

Name: _____

Title: _____

SAMPLE